ACCESSING SERVICES AND RESOURCES

FOR PERSONS WITH SUSPECT OR ACTIVE TUBERCULOSIS DISEASE OR LATENT TUBERCULOSIS INFECTION (LTBI)

GUIDELINE for ESTABLISHING EFFECTIVE
POLICIES, PROCEDURES AND PRACTICES

This guideline has been developed by the Wisconsin Department of Health and Family Services as a tool to assist local health departments in updating or developing policies, procedures and practices for the care of clients with tuberculosis. It serves as a model and needs to be adapted according to each local health department's needs. Items that provide additional information, education or reference are in italics or are otherwise highlighted, such as in boxes. These portions are included for use during the adaptation process, are not written in policy and procedure language and are not required to be in the local health department's final policy and procedure documents.

Because it is not possible for any guideline to address all potential situations for individuals, clinical judgement must always be exercised. All other legal requirements must be followed to ensure "due process" and all laws pertaining to minors and/or persons with guardians are to be followed when implementing this guideline.

When federal regulations, state statutes, administrative codes or CDC endorsed guidelines pertaining to tuberculosis are revised, the Division of Public Health will notify local health departments of the availability of these resources. Local health departments need to update their policies, procedures and practices accordingly to remain consistent with ongoing changes in legal requirements and tuberculosis care, for both the health of the affected individuals and the health of the public.

GUIDELINE for POLICY DEVELOPMENT

I. Terms and Definitions
II. Purpose
III. Persons Affected/Responsible
IV. Suggested Policy Language
V. Legal Authority
VI. References

GUIDELINE for PROCEDURE DEVELOPMENT

I. Terms and Definitions
II. Purpose
III. Persons Affected/responsible
IV. Suggested Procedure Language
V. References

Note: Attachments and tools are integrated throughout the procedure guideline, not in a separate appendix.

GUIDELINE for ESTABLISHING EFFECTIVE PRACTICE	Reviewed/Revised:
Accessing Services and Resources for Persons with suspect or active tuberculosis disease or Latent tuberculosis infection (LTBI)	Signatures & Dates: _____ _____ _____ _____ _____ _____
_____ Health Department Original Effective Date _____ Approved by _____	_____ _____ _____ _____

GUIDELINE for POLICY DEVELOPMENT

I. Terms and Definitions:

Alien/Immigrant/Refugee Classifications –

Alien – Any person who is not a citizen of the U.S.

Documented Alien – An alien who is legally residing in the U.S. They have documents such as a valid social security card, a permanent resident card (lay term "green card")

Undocumented Alien – An alien who is residing in the U.S. without legal documentation such as a valid social security card or a permanent resident card; also referred to as "illegal aliens"

K-1 Fiancé – An alien who is engaged to a U.S. citizen and intends to marry him or her within 90 days of arrival in the U.S.

Immigrant – A person who is not a citizen of the U.S. who is admitted *legally* as either an actual, or a prospective permanent resident, or as a legal temporary resident

Refugee – A person who is not a citizen of the U.S. who is given *legal status* of "refugee" before entering the U.S. and cannot return to the country of origin for fear of persecution

Class A Immigrant/Refugee – Individual has *confirmed* TB disease. Chest x-ray taken abroad is consistent with active disease, person should be on medications for disease but was smear negative at departure and considered safe to travel at that time

Class B-1 Immigrant/Refugee – Individual has an abnormal chest x-ray taken abroad that is *suggestive* of active tuberculosis but had a negative sputum smear for AFB prior to departure and was considered not infectious and safe to travel at that time; person may be on medications for active disease

Class B-2 Immigrant/Refugee – Individual has had an abnormal overseas chest x-ray suggestive of *inactive* tuberculosis; overseas sputum specimens were *not* tested

Class B-3 Immigrant/Refugee – Individual has a chest x-ray done abroad that shows old or healed tuberculosis; overseas sputum specimens were *not* tested

Case Reporting – Informing the state or local health department when a new case or occurrence of TB disease has been diagnosed or is suspected according to the requirements of Wisconsin Administrative Rule, HFS 145.03 and HFS 145.04.

Clinically Evaluated – Medical exam that may include a skin test, a chest radiograph, review of TB signs and symptoms and collection of clinical specimens when appropriate.

Culture Confirmed Tuberculosis – Tuberculosis disease that has been confirmed by culture-positive identification on a clinical specimen.

Extrapulmonary tuberculosis – Tuberculosis in any part of the body other than the lungs.

High-risk tuberculosis – an infection with tuberculosis that is highly likely to progress to active disease and may easily become infectious if it remains untreated.

Immunosuppression – The suppression of natural human responses to infection as caused by disease, malnutrition, or medical treatment involving drugs or irradiation.

Infection – The condition in which organisms capable of causing disease enter the body and elicit a response from the host's immune system. TB infection may or may not lead to active TB disease, however persons with infection remain at life-long risk of developing active disease if their infection goes untreated. Also known as latent tuberculosis infection (LTBI).

Infectious tuberculosis – Tuberculosis disease of the respiratory tract, capable of producing infection or disease in others as demonstrated by the presence of acid-fast bacilli in the sputum or bronchial secretions or by chest radiograph and clinical findings.

Laryngeal tuberculosis – Tuberculosis of the larynx; often considered more infectious than pulmonary TB; organisms are generally exhaled by the person with the disease.

Latent TB infection (LTBI) – Infection with *M. tuberculosis*, usually detected by a positive PPD skin test result, in a person who has no symptoms of active TB and is not infectious. Tubercle bacilli are present in the body but the disease is not clinically active; same as TB infection.

Report of Verified Case of Tuberculosis (**RVCT) –** Standard case report form used to report tuberculosis cases to the CDC.

Suspect tuberculosis – An illness marked by symptoms such as prolonged cough, prolonged fever, hemoptysis; compatible radiographic or medical imaging findings; or laboratory tests that may be indicative of tuberculosis.

Medicaid Tuberculosis-Related Benefit (MA TR Benefit) – A Medicaid benefit that covers TB clinical services for individuals meeting the financial eligibility requirements who are infected with tuberculosis or those who have active disease.

Transmission – The spread of an infectious agent from one person to another. The likelihood of transmission is directly related to the duration and intensity of the exposure to *M. tuberculosis* and the vulnerability of the person who has been exposed.

II. Purpose:

The purpose of this policy is to ensure accurate and timely reporting of TB suspects and cases of active disease and to ensure that all persons affected by tuberculosis receive the services they need and that the health of the public is protected.

III. Persons Affected/Responsible:

This policy will be carried out by _____ under the direction of
(List staff positions affected)
the health officer of the _____ health department.
City/County

IV. Suggested Policy Language:

The _____ Health Department will ensure immediate reporting of all suspect and active disease cases according to Wis. Stats. s. 252.07 and Wisconsin Administrative Code, HFS 145.04. The Health Department will ensure that case finding, diagnosis and treatment of suspect or confirmed active tuberculosis disease are carried out according to the protocols established by the CDC and the State TB Program to protect the health of the public. The Health Department will promote accurate identification and treatment of latent tuberculosis infection, and foster accessibility to all services and resources for those who are affected by tuberculosis.

V. Legal Authority:

The local health officer has authority under Wisconsin Statutes, Wis. Stats. ss. 252.07(8) & 252.07(9) and Wisconsin Administrative Code HFS 145.05 (1).

VI. References Used for State Guideline Development

[*The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy and procedure document.*]

1. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395

2. American Thoracic Society. **Treatment of tuberculosis and tuberculosis infection in adults and children.** American Journal of Respiratory and Critical Care Medicine, 1994; 149: 1359-74.

3. American Thoracic Society. 1997. **Supplement: Diagnosis and Treatment of Disease Caused by Nontuberculous Mycobacteria**. Am. J. Respir. Crit. Care Med. 156(2): S1-S25

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5. California Department of Health Services and Executive Committee of the California Tuberculosis Controllers Association. **Guidelines for Follow-Up & Assessment of Persons with Class B1/B2 TB.** 8/10/99

6. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know**. Fourth Edition, 2000.

7. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**. MMWR April, 2000;49 (No. RR-6).

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9. Centers for Disease Control and Prevention. **Forging Partnerships to Eliminate Tuberculosis**. 1995.

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11. Centers for Disease Control and Prevention. **Self-Study Modules on Tuberculosis**. Modules 1-5, 1995. Modules 6-9, 2000.

12. Chin, J, ed. **TUBERCULOSIS**. In: Control of Communicable Diseases Manual. 17th ed. Washington, DC: American Public Health Association, 2000: 521-532.

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Association, 2000: 530-532.

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15. Falkinham III, J.O. 1996. **Epidemiology of Infection by Nontuberculous Mycobacteria**. Clin. Micro. Rev. 9(2): 177-215.

16. **Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health care facilities**, 1994. MMWR 1994; 43(RR-12).

17. Metchock, B.G., F.S. Nolte and R.J. Wallace. 1999. **Mycobacterium.** In: Manual of Clinical Microbiology, p399-437. 7th Ed. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover and R.H. Yolken (ed). ASM Press, Washington, D.C.

18. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Patient Care**, 1997.

19. New Jersey Medical School National Tuberculosis Center, **Tuberculosis Glossary**, 1995

20. North Carolina Division of Epidemiology, Department of Health and Human Services. **North Carolina Tuberculosis Policy Manual**. 1997.

21. Pickering, L., ed. **Diseases Caused by Nontuberculous Mycobacteria**. In: 2000 Red Book: Report of the Committee on Infectious Diseases, 25th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2000, 613-618.

22. Pickering, L.K., ed. **Tuberculosis**. In: 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2000, 593-613.

23. **"Tuberculosis"** DPH Disease Fact Sheet Series, POH 4432. (http://www.dhfs.state.wi.us/healthtips/BCD/Tuberculosis.htm).

24. **TB Fact Sheet Series** found at http://www.dhfs.state.wi.us/dph_bcd/TB/Resources/TB_resources2.htm

    Sputum Conversion during TB Treatment, (POH 7131)
    Rifater and Rifamate in the Treatment of TB (POH 7133)
    Tuberculin Skin Testing for Suspected TB (POH 7134)
    The Importance of Rifampin (POH 7135)
    False-Positive Cultures for *Mycobacterium tuberculosis* (POH 7137*)*

25. Wayne, L.G. and R.C. Good, **The "Atypical" Mycobacteria: Recognition and Disease Association.** CRC Critical Rev. Micro. 12:185-222.

26. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases,** Chapter 145.

27. Wisconsin Division of Public Health. **Infection Control Plan for Local Health Departments** (developed as a template for local health departments). 1998.

28. Wisconsin Division of Public Health. **Tuberculosis Infection Control Plan** (developed as a template for county jails). 1998.

29. Wisconsin Epidemiology Bulletin (WEB) 1996; 17(2), **BCG Vaccination and Tuberculosis**.

30. **Wisconsin Statutes, Communicable Diseases**; ss. 252.06 – 252.07; 1997-98.

31. **Wisconsin TB Program Strategic Plan for Elimination of TB in Wisconsin,** 2001.

32. Wolinsky, E. 1992. State of the art clinical article: **Mycobacterial Diseases Other Than Tuberculosis**. Clin. Infect. Dis. 15:1-12

33. **World Wide Web addresses**, National Model TB Centers & CDC:

    Harlem Model Center – www.harlemtbcenter.org
    New Jersey Model Center – www.umdnj.edu/ntbc
    San Francisco Model Center – www.nationaltbcenter.edu
    Centers for Disease Control and Prevention, CDC, Atlanta – www.cdc.gov

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Transmission – The spread of an infectious agent from one person to another. The likelihood of transmission is directly related to the duration and intensity of the exposure to *M. tuberculosis* and the vulnerability of the person who has been exposed.

II. Purpose:

The purpose of this procedure is to guide staff in timely reporting of suspect and confirmed active tuberculosis and in accessing the various services and resources that are available for persons with suspect or active tuberculosis disease or latent tuberculosis infection. This procedure will enable the health department staff to carry out the activities required for tuberculosis control and for the protection of the health of the public as specified in Wisconsin statutes and rules and according to current standards of practice.

III. Persons Affected/Responsible:

This procedure will be carried out by _____ under the direction
(List staff positions affected)
of the health officer of the _____ health department.
City/County

IV. Suggested Procedure Language:

This procedure is divided into four parts:

A. WI Tuberculosis Program – Communication, Services & Resources for
   - Persons with Suspect or Confirmed Active TB Disease
   - Persons with Latent Tuberculosis Infection (LTBI)
   - Persons with special reporting requirements and needs (e.g. immigrants and refugees)

B. Receipt, Storage and Control of TB Medications in the Local Health Department.

C. Accessing Wisconsin State Laboratory of Hygiene Services (WSLH)

D. Medical Assistance (MA) Benefits for Persons with Tuberculosis (TB)

A. WI Tuberculosis Program – Communication, Services & Resources

- **Persons with Suspect or Confirmed Active TB Disease**

1. **Reporting** a person who is a suspect or a confirmed case of active tuberculosis disease

a. Ensure that policies, procedures and practices are in place at the health department that ensure the collection of critical information during the intake process.

b. Refer to health department policies, procedures and practices or state TB guidelines for implementing any necessary isolation or confinement and the contact or source case investigation.

c. Evaluate all data elements when a DPH 4151, Acute & Communicable Disease Case Report comes to the health department from a health care provider. **Do not delay health department reporting to the state TB Program/Epidemiologist if information is not yet complete.**

d. Complete a DPH 4151 form when you receive a verbal/phone report of a person with **suspect or active TB** disease and you have not yet received a 4151 from them. Administrative Code 145.04(2)(b) requires that reports be verbal or written. An initial telephone report from the health care provider to the local health department is adequate to satisfy the immediate reporting requirement for the health care provider. The local health department then reports to the WI TB Program.

Insert the multiple copy 4151 here for staff education and orientation purposes. Educate staff in accessing and using it electronically when it becomes available.

e. Assess and document all available information regarding the person affected, report to the state TB program **immediately,** and complete and submit the DPH 4151. Instructions are on the back of the 4151. The local health department is responsible for securing **complete** information even if a report or a 4151 begun by a health care provider is incomplete.

f. Contact the health care provider reporting the person for the missing information. Follow health department policies, procedures and legal documentation standards of practice for correctly adding additional information to an incomplete report.

g. Contact the Regional Public Health Office if there are any difficulties securing information. Only one report form is necessary; it must be complete.

h. Send the DPH 4151 form within 24 hours as required by appendix A of Wisconsin Administrative Code Chapter HFS 145 for Category I diagnoses including tuberculosis. Immediate faxing of the 4151 is an acceptable substitute for both immediate reporting to the state and mailing of the 4151. If TB is later ruled out, communicate that fact when confirmed.

i. Perform a preliminary quality assurance check to ensure that you are providing appropriate care and that you are documenting and reporting as required. Review the data elements and information on the following tools for this process:

- DPH Report Form 4151, Acute & Communicable Disease Case Report and Instructions

- EPINET Manual Information on:

    - TUBERCULOSIS
    - NONTUBERCULOSIS MYCOBACTERIA
      (Updated periodically, available on the Health Alert Network – HAN)

- Tuberculosis Reporting Made Simple – TB Program handout

- TB Suspect Case Data form and Instructions

    - The TB Suspect Case Data form is not a required form, however the information on it **is** required information. It is used internally by the WI TB Program so you may find it useful to ensure completeness of your delivery of care, data and reports.
    - There is some duplication of information on these forms, however, **only the 4151 is required to be submitted.**
    - You may adapt the Suspect Case Data form for your clinical records and retain your original in the client's record.

DEPARTMENT OF HEALTH & FAMILY SERVICES
Division of Public Health
DPH 4151 (Rev. 07/00)

ACUTE & COMMUNICABLE DISEASE CASE REPORT

Information for completing this form on reverse side

STATE OF WISCONSIN
s. 252.05, Wis. Stats
(608) 267-9003

DEMOGRAPHIC DATA PATIENT INFORMATION

Case Identification for all Category I and II diseases

Patient's Name (Last, First, Middle Initial)	Date of Birth (mm/dd/yyyy)	Age	Gender ☐ Male ☐ Female
Patient's Address			Telephone No. ( )
City	State	Zip Code	County of Residence
Patient's Parent / Guardian if patient is a minor (Not needed for STD)	Patient's Employer & Occupation or School, Day Care, Institution		
Patient pregnant? ☐ Yes ☐ No If Yes, Due date (mm/dd/yyyy)	Patient died of this illness? ☐ Yes ☐ No	Patient hospitalized? ☐ Yes ☐ No	
Race ☐ White ☐ Black ☐ Asian or Pacific Islander ☐ Native American ☐ Other, specify		Ethnic Origin ☐ Hispanic ☐ Non-Hispanic	

MORBIDITY DATA

Disease / Organism	Date of onset (mm/dd/yyyy)	Specimen Type	Outbreak related? ☐ Yes ☐ No ☐ Unknown	Underlying medical condition? ☐ Yes, Specify_____ ☐ No ☐ Unknown

Type of Test or Immunization. Include confirmatory laboratory data and immunization dates

	Date (mm/dd/yyyy)	Results

SEXUALLY TRANSMITTED DISEASES

Complete appropriate section for specific disease(s)

☐ Syphilis	☐ Gonorrhea ☐ Chlamydia	☐ Other STD
☐ Primary (chancre present) ☐ Secondary (skin lesions, rash, etc.) ☐ Early Latent (asymptomatic, less than 1 yr duration) ☐ Late Latent (over 1 yr duration) ☐ Neurosyphilis ☐ Cardiovascular ☐ Other ☐ Congenital	☐ Asymptomatic ☐ Uncomplicated Urogenital (Urethritis,Cervicitis) ☐ Salpingitis (PID) ☐ Ophthalmia/Conjunctivitis ☐ Other (Arthritis, skin lesions, etc.) ☐ Resistant Gonorrhea ☐ Penicillinase – Producing ☐ Other	☐ Chancroid ☐ Primary genital herpes infection ☐ Other STD Salpingitis (PID) Type and Amount of Treatment

Has patient been treated? ☐ Yes ☐ No

Date(s) of Treatment (mm/dd/yyyy)

ENTERIC DISEASES AND HEPATITIS B

Salmonella, Shigella, Giardia, Campylobacter, Yersinia, Hepatitis A, and Amebiasis

Check below if patient:

Yes	No	Unknown	
☐	☐	☐	is a food handler.
☐	☐	☐	attends or works at a day care center.
☐	☐	☐	is a health care worker.
☐	☐	☐	drinks unpasteurized milk.
☐	☐	☐	is in contact with animals. If yes, specify:_____

Hepatitis B Results

HBsAg	☐ Positive	☐ Negative
anti-HBs	☐ Positive	☐ Negative
anti-HBc	☐ Positive	☐ Negative
anti-HBc-IgM	☐ Positive	☐ Negative

TUBERCULOSIS

Mycobacteriology	X-ray	Mantoux Tuberculin Test	Treatment
Specimen type and Date collected (mm/dd/yyyy)	☐ Not done ☐ Normal ☐ Abnormal Date _____	☐ Not Done Date Done (mm/dd/yyyy)	☐ Isoniazid ☐ Rifampin ☐ Pyrazinamide ☐ Ethambutol ☐ Other, specify
Smear ☐ Positive ☐ Negative ☐ Pending ☐ Not done Culture ☐ Positive ☐ Negative ☐ Pending ☐ Not done	Check one: ☐ Stable ☐ Worsening ☐ Improving Check one: ☐ Cavitary ☐ Noncavitary	Result (w / mm induration) ☐ Positive _____ mm ☐ Negative _____ mm If negative, anergic? ☐ Yes ☐ No	Date started (mm/dd/yyyy)
Report Date (mm/dd/yyyy)			
If culture positive ☐ *M. tuberculosis* complex ☐ Atypical Mycobacteria, Specify:_____	Previously diagnosed with TB ☐ Yes, Year_____ ☐ No ☐ Unknown	Patient's country of origin	Date arrived in U.S.

WEEKLY REPORTABLE & COMMENTS

Weekly Reportable Diseases Category II (Saturday through Friday)

Varicella (Chickenpox) Number of cases _____ Week ending / Date(mm/dd/yyyy)

Comments:

REPORTING SOURCE (REQUIRED)

Name and Address of Person or Agency Reporting	Telephone No. ( )
Name and Address of Attending Physician	Telephone No. ( )

Complete and make three (3) copies: Copy A - State Epidemiologist, Copy B - Local Public Health Agency, Copy C - Patient Medical Record.

Accessing Services and Resources for Persons with Tuberculosis

TELEPHONE For Disease Consultation or For General Information (608) 267-9003	Instructions for Completing Attached ACUTE AND COMMUNICABLE DISEASE CASE REPORT DOH 4151 (Rev. 12/99)	Issued by Bureau of Communicable Diseases Wisconsin Division of Public Health PO Box 2659 Madison, WI 53701-2659

GENERAL INSTRUCTIONS

Diseases listed under categories I, II, IV are to be reported to the *local health officer located in the local public health agency of the patient's place of residence*. The catego III disease must be reported directly to the state epidemiologist. Use the attached 3-part carbon interleaved form for this purpose. Complete Section A, *Demographic and Morbidity Data*, for diseases in categories I, II, and III. For diseases followed by two asterisks (**), give vaccination history. Follow-up epidemiologic information may be requested by local or state public health officials. Report the number of *Chickenpox* cases (Category IV) weekly by aggregates on the same form as a category I, II, III diseases. Complete Section G, person reporting, for *ALL* categories. Send copy "A" and copy "B" to the local health officer. Copy "C" may be retained with the patient's record.

REPORT THE FOLLOWING DISEASES TO YOUR LOCAL HEALTH AGENCY

CATEGORY I:

The following diseases are of urgent health importance and shall be reported **IMMEDIATELY** by telephone to the patient's local health officer upon identification of a cas suspected case. Complete and mail an Acute and Communicable Disease Case Report (DOH 4151) to the local health officer within 24 hours. Public health intervention is expected as indicated. See s. HFS 145.04 (3) (a).

Anthrax [1,4,5]
Botulism [1,4]
Botulism, infant [1,2,4]
Cholera [1,3,4]
Diphtheria [1,3,4,5]
Foodborne or waterborne outbreaks [1,2,3,4]
Haemophilus influenzae invasive disease, (including epiglottitis) [1,2,3,5]
Hepatitis A [1,2,3,4,5]
Measles [1,2,3,4,5]
Meningococcal disease [1,2,3,4,5]
Pertussis (whooping cough) [1,2,3,4,5]
Plague [1,4,5]
Poliomyelitis [1,4,5]
Rabies (human) [1,4,5]
Ricin toxin [4,5]
Rubella [1,2,4,5]
Rubella (congenital syndrome) [1,2,5]
Smallpox [4,5]
Tuberculosis [1,2,3,4,5]
Yellow Fever [1,4]

CATEGORY II:

The following diseases shall be reported to the local health officer on an Acute and Communicable Disease Case Report (DOH 4151) or by other means within 72 hours of identification of a case or suspect case. Public health intervention is expected as indicated. See s. HFS 145.04 (3) (b).

Amebiasis [1,3,4]
Arboviral infection (encephalitis / meningitis) [1,2,4]
Babersiosis [4,5]
Blastomycosis [5]
Brucellosis [4]
Campylobacteriosis infection [3,4]
Cryptosporidiosis [1,2,3,4]
Cyclosporiasis [1,4,5]
E. coli 0157:H7 [1,2,3,4]
Encephalitis, viral (other than arboviral)
Ehrlichiosis [1,5]
Giardiasis [3,4]
Hemolytic uremic syndrome [1,2,4]
Hepatitis B [1,2,3,4,5]
Hepatitis C [1,2]
Hepatitis non-A, non-B, (acute) [1,2]
Hepatitis D [2,3,4,5]
Histoplasmosis [5]
Kawasaki disease [2]
Legionellosis [1,2,4]
Leprosy [1,2,3,4,5]
Leptospirosis [4]
Listeriosis [2,4]
Lyme disease [1,2]
Malaria [1,2,4]
Mumps [1,2,4,5]
Meningitis,bacterial (other than Haemophilus influenzae or meningococcal) [2]
Meningitis, viral (other than arboviral)
Mycobacterial disease (nontuberculous)
Psittacosis [1,2,4]
Q fever [4,5]
Reye syndrome [2]
Rheumatic fever (newly diagnosed) [5]
Rocky Mountain spotted fever [1,2,4,5]
Salmonellosis [1,3,4]
Sexually transmitted diseases:
- Chancroid [1,2]
- Chlamydia trachomatis infection [2,4,5]
- Genital herpes infection
- Gonorrhea [1,2,4,5]
- Pelvic inflammatory disease [2]
- Syphilis [1,2,4,5]

Shigellosis [1,3,4]
Tetanus [1,2]
Tetanus [1,2]
Toxic shock syndrome [1,4]
Toxic substance related diseases:
- Infant methemoglobinemia
- Lead intoxication (specify Pb levels
- Other metal and pesticide poisoning

Toxoplasmosis
Trichinosis [1,2,4]
Tularemia [1,4]
Typhoid fever [1,2,3,4]
Typhus fever [4]
Varicella (chickenpox)—report by number of cases only
Yersiniosis [3,4]

Suspected outbreaks of other acute or occupationally-related diseases
And other enterohemorrhgic E. coli, enteropathogenic E. coli, enteroinvasive E. coli, E. coli [1,2,3,4]

CATEGORY III:

The following diseases shall be reported to the state epidemiologist on an AIDS case report (DOH 4265) or a Wisconsin Human Immunodeficiency Virus (HIV) Infection Confidential Case Report (DOH 4338) or by other means within 72 hours after identification of a case or suspected case. See s. 252.15 (7) (b), Stats., and s. HFS 145.04 (3)

Acquired Immune Deficiency Syndrome (AIDS) [1,2,4]
Human immunodeficiency virus (HIV) infection [2,4]
CD4+ T-lymphocyte <200/uL, or CD4+ T-lymphocyte percentage of total lymphocytes of <14

KEY:

[1] Infectious diseases designated as notifiable at the national level.
[2] Wisconsin or CDC follow-up form is required. Local health departments have templates of these forms in the Epinet manual.
[3] High-risk assessment by local health department is needed to determine if patient or member of patient's household is employed in food handling, day care or health care.
[4] Source investigation by local health department is needed.
[5] Immediate treatment is recommended, i.e., antibiotic or biologic for the patient or contact or both.

WISCONSIN STATUTE CHAPTER 252.05 AND ADMINISTRATIVE RULE CHAPTER HSS 145 REQUIRE REPORTING OF COMMUNICABLE DISEASES.

Persons reporting include any person licensed under ch 441 and 448, stats., or any other person having knowledge that a person has a communicable disease such as;

a. a person in charge of infection control at a health care institution.
b. School nurses, principals of schools and day care center directors.
c. Laboratory directors.

For further information see Wisconsin Administrative Rule HSS 145.

Excerpts from WI EPINET Manual. March, 2001 (Refer to EPINET Manual for complete information – updated periodically on the Health Alert Network - HAN.)

TUBERCULOSIS

I. IDENTIFICATION

A. CLINICAL DESCRIPTION: A bacterial disease usually affecting the lungs (pulmonary TB) caused by organisms in the *Mycobacterium tuberculosis* complex (*M. tuberculosis*, *M. bovis*, *M. africanum*). Other parts of the body (extrapulmonary TB) can also be affected (e.g., brain, lymph nodes, kidneys, bones, joints, larynx, intestines, eyes). Systemic symptoms include low-grade fever, night sweats, fatigue, weight loss. In pulmonary or laryngeal TB, there may also be hemoptysis, a persistent and productive cough, chest pain, and shortness of breath.

B. REPORTING CRITERIA: Laboratory confirmation of tuberculosis or a clinical diagnosis without laboratory confirmation.

C. WISCONSIN CASE DEFINITION: A case that meets the following for laboratory confirmation or clinical diagnosis:

1. Laboratory Confirmation by one of the following methods:

- Isolation of *M. tuberculosis* or *M. tuberculosis* complex organisms from a clinical specimen. Use of rapid identification techniques for *M. tuberculosis* such as DNA probes and mycolic acid high-pressure liquid chromatography (HPLC) performed on a culture from a clinical specimen are acceptable under this criteria.
- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test. Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species. However, for surveillance purposes, CDC will accept results obtained from nucleic acid amplification (NAA) tests approved by the FDA and used in accordance with the approved product labeling on the package insert. Current FDA approved NAA tests are only approved for smear-positive respiratory specimens (e.g., MTD).
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained.

2. Clinical Diagnosis:

- Signs and symptoms compatible with tuberculosis, such as abnormal, unstable (worsening or improving) chest x-ray, or clinical evidence of current disease, **AND**
- Resolution of symptoms following treatment with two or more anti-tuberculosis medications, **AND**
- Completed diagnostic evaluation.

NOTE: A positive tuberculin skin test may provide further evidence of TB; however, due to anergy, a negative skin test does *not* rule out the possibility of active TB.

II. ACTIONS REQUIRED / PREVENTION MEASURES

A. WISCONSIN DISEASE SURVEILLANCE CATEGORY I: REPORT TO THE LOCAL HEALTH DEPARTMENT **IMMEDIATELY** upon recognition of a case or suspected case by telephone and mail (or fax) the Acute and Communicable Diseases Case Report (DPH 4151) within 24 hours. Public health intervention expected.

B. EPIDEMIOLOGY REPORTS REQUIRED:

- Acute and Communicable Diseases Case Report (DPH 4151).
- If requesting state-funded medication: Antituberculosis Therapy Program Initial Request for Medication (DPH 4000).
- A completed Report of Verified Case of Tuberculosis (CDC 72.9 A and B) will be sent to the LHD for review upon confirmation of a confirmed case.

C. PUBLIC HEALTH INTERVENTIONS:

- For patients with pulmonary and laryngeal tuberculosis, control of infectivity is best achieved by prompt specific drug therapy.
- Patients must remain isolated (at home or in a negative pressure room designated for TB patients) until three consecutive smears are negative for AFB from sputum specimens collected on different days, **AND** the patient has been on appropriate therapy for at least two weeks, **AND** there is evidence of clinical improvement.
- Investigation of known contacts and source of infection.
- Initial tuberculin testing of all household members and other close contacts, with repeat skin testing of those with negative skin tests 90 days post exposure.
- Multiple Drug Resistant (MDR) cases must remain in isolation until three consecutive cultures are negative for MTB from sputum specimens collected on different days.

Excerpts from WI EPINET Manual, March, 2001 (Refer to EPINET Manual for complete information – updated periodically on the Health Alert Network - HAN.)

NONTUBERCULOUS MYCOBACTERIA

I. IDENTIFICATION

A. CLINICAL DESCRIPTION: Clinical syndromes associated with the pathogenic species of non-tuberculous (atypical) mycobacteria can be classified as follows (refer to attached chart for additional information):

- Disseminated disease in the presence of severe immune deficiency as in AIDS.
- Pulmonary disease resembling tuberculosis.
- Lymphadenitis, primarily cervical.
- Skin ulcers.
- Post-traumatic wound infections.
- Nosocomial disease:
  1. Surgical wound infections: Sternal following cardiac surgery, mammoplasty wounds.
  2. Catheter-related infections: Bacteremia, peritonitis and post-injection abscesses.
- Crohn's disease.

B. REPORTING CRITERIA: Laboratory confirmation.

C. LABORATORY CRITERIA FOR CONFIRMATION:

- Isolation of non-tuberculous mycobacteria from the affected area of the body, **AND**
- Evidence of clinical disease for which no other diagnosis has been made

NOTE: A single isolate of non-tuberculous mycobacteria without compatible clinical evidence of disease does not meet the case definition.

D. WISCONSIN CASE DEFINITION: Laboratory confirmation of non-tuberculous mycobacteria with evidence of compatible clinical disease.

II. ACTIONS REQUIRED / PREVENTION MEASURES

A. WISCONSIN DISEASE SURVEILLANCE CATEGORY II: Report to the local health officer on an Acute and Communicable Diseases Case Report (DPH 4151) or by telephone within 72 hours of the identification of a case or suspected case. No public health intervention expected.

B. EPIDEMIOLOGY REPORTS REQUIRED: Acute and Communicable Diseases Case Report (DPH 4151).

C. PUBLIC HEALTH INTERVENTIONS: None.

Non-tuberculous mycobacteria

Organism	Where found	Diseases	Person-to-person transmission
M. avium complex (MAC or MAIC): a) *M. avium* b) *M. intracellulare* c) *M.* species	Widely distributed in nature (water, soils, birds, other animals, dust)	Pulmonary in immunocompetent, disseminated in immunosuppressed	NO
Mycobacterium scrofulaceum	Environmental water	Cervical lymphadenitis in children	NO
Mycobacterium kansasii	Water	Chronic pulmonary disease in humans (may resemble disease caused by *M. tuberculosis*)	Minimal risk
M. xenopi	Hot water supplies	Pulmonary in immunocompetent, disseminated in immunosuppressed	NO
M. marinum	Environmental waters, aquariums, insufficiently chlorinated swimming pools	"Swimming pool granuloma", localized infections of the skin at sites of cuts or abrasions, disseminated disease in the immunosuppressed	NO
M. fortuitum complex includes a) *M. fortuitum* b) *M. peregrinum* c) *M. chelonae* d) *M. abscessus*	Soil and water	Infections ranging from localized wound infections to respiratory disease to serious disseminated infections	NO
M. simiae complex includes: a) *M. simiae* b) *M. genavense* c) *M. triplex* d) *M. lentiflavum* e) *M.* species SAV	Water	Pulmonary in immunocompetent, disseminated in immunosuppressed	Possibly

M. szulgai	Environment	Pulmonary infections in almost all cases; dissemination found in AIDS patients	NO
M. terrae complex includes: a) *M. terrae* b) *M. triviale* c) *M. nonchromogenicum*	Soil	Usually does NOT cause disease Disease in the lungs, joints, GI tract and genitourinary tract occur in 10% of all isolations	NO
M. malmoense		Pulmonary disease, dissemination in AIDS patients	NO
M. ulcerans	Unknown, thought to be water	Necrotizing disease in humans, invading skin, muscle tissues and bone; "Buruli ulcers"	NO
M. haemophilum	Environment	Granulomatous infections of the skin	NO
Mycobacterium gordonae	Water, especially tap water Common laboratory contaminant	Very rarely causes disease	NO
M. mucogenicum (previously called MCLO or "*M. chelonae*-like organisms")	Environmental waters	Rarely causes human disease	NO
M. paratuberculosis	Water, unpasteurized milk	Johne's disease in cattle, possible link to Crohn's disease in humans	NO
M. smegmatis	Environment	Disease is uncommon, may cause skin or soft tissue infections	NO

<u>Other mycobacteria (uncommon)</u>

M. asiaticum	*M. farcingenes*	*M. neoaurum*	*M. flavescens*
M. branderi	*M. gastri*	*M. shimoidei*	*M. senegalense*
M. aurum	*M. goodii*	*M. thermoresistible*	
M. celatum	*M. interjectum*	*M. tokaiense*	
M. fallax	*M. intermedium*	*M. vaccae*	

DEPARTMENT OF HEALTH & FAMILY SERVICES
Division of Public Health
DPH 42001 (04/01)

TB SUSPECT CASE DATA

Client information is confidential under Wis. Stat. 146.82(1)

STATE OF WISCONSIN
Bureau of Communicable Diseases
ss. 252.05, Wis. Stats.

FOR INTERNAL USE ONLY: ☐ IN TIMS

Date Local Health Department Contacted (mm/dd/yyyy)	Referral Source	Referral Telephone No. ( )	Reported To LHD Within 24 Hrs ☐ Yes ☐ No
Name Of Patient		Date Of Birth (mm/dd/yyyy)	Gender ☐ Female ☐ Male / Race
Address		Patient Telephone No. ( )	Patient occupation last 2 years
Local Health Department		Public Health Nurse (PHN)	
Telephone No. of PHN ( )		Date Reported to State TB Program (mm/dd/yyyy)	
Name of Primary Physician		Telephone No. ( )	
Name of Other Physician (Pulmonary Specialist, etc.)		Telephone No. ( )	

CHEST X-RAY

Date(s) taken (mm/dd/yyyy) ☐ Normal ☐ Abnormal

Results of X-ray ☐ Cavitation ☐ Infiltrate ☐ Opacity ☐ Granulomas ☐ Nodule

Location ☐ Apex ☐ LUL ☐ RUL ☐ RLL ☐ LLL ☐ LL ☐ RL

Comments:

BACTERIOLOGY

Laboratory where specimen was sent

Specimen Information

		Smear			MTD / PCR			Culture		
Date Collected	Source	POS	Results	NEG	POS	NEG	Comment	POS	NEG	Date Identified
		☐		☐	☐	☐		☐	☐	
		☐		☐	☐	☐		☐	☐	
		☐		☐	☐	☐		☐	☐	
		☐		☐	☐	☐		☐	☐	

Drug Sensitivities

INH	☐ SENS	☐ RES	EMB	☐ SENS	☐ RES
RIF	☐ SENS	☐ RES	OTHER(S)	☐ SENS	☐ RES
PZA	☐ SENS	☐ RES		☐ SENS	☐ RES

TREATMENT

Date Started (mm/dd/yyyy)	Patient's weight		Regimen Duration	DOT ☐ Yes ☐ No If yes, where?	
Drugs	INH	RIF	PZA	EMB	OTHER
Dose(s) and Frequency					

PATIENT HISTORY

Date of PPD (mm/dd/yyyy)

Results (induration) mm

Homeless in the past year? ☐ Yes ☐ No ☐ Unk

Date of Previous PPD (mm/dd/yyyy)

Results (induration) mm

Non-injection drug use within the past year? ☐ Yes ☐ No ☐ Unk
Injection drug use within the past year? ☐ Yes ☐ No ☐ Unk

If previously tested, list city and state

Alcohol use within the past year? ☐ No ☐ Regular ☐ Excess
How much and how often?

If previous PPD was positive, was treatment for TB infection taken?
☐ Yes ☐ No If yes, was treatment completed? ☐ Yes ☐ No

Smoker? ☐ Yes ☐ No If yes, how much and how long?

Patient history of TB disease? ☐ Yes Year (yyyy) ☐ No
Family history of TB disease? ☐ Yes ☐ No
If yes, who and when (yyyy)

Foreign born? ☐ Yes ☐ No If yes, country of origin_____
Month and year arrived in USA_____
Type of VISA ☐ Immigrant / Refugee ☐ Student ☐ Work
☐ Visitor / Tourist
☐ Other Explain_____

Signs and Symptoms ☐ cough ☐ fever ☐ hemoptysis
☐ night sweats ☐ weight loss ☐ loss of appetite

Duration/ dates (mm/dd/yyyy) _____

HIV Status ☐ positive ☐ negative ☐ not tested
Date tested (mm/dd/yyyy)
If not tested, Why? ☐ not offered ☐ refused ☐ other

Recent foreign travel? ☐ Yes ☐ No
If yes, where and when (mm/yyyy)

Other risk factors? ☐ diabetes ☐ kidney disease ☐ liver disease
☐ immunosuppressed ☐ cancer List type_____
☐ corticosteroid use How much and how long?_____
☐ other risk factors_____

Resident of long-term care or correctional facility? ☐ Yes ☐ No
If yes, which one and how long?

Disposition ☐ pulmonary ☐ extrapulmonary ☐ not a case
If extrapulmonary, site_____
Case verified by ☐ laboratory ☐ clinical improvement

Instructions for completing
TB SUSPECT CASE DATA

This form is used to gather data on tuberculosis (TB) suspect and confirmed cases. The Department of Health and Family Services requires some of the information in accordance with Wis. Stats. s. 252.05(4) and other data elements are incorporated to assist with TB elimination efforts. Please fill out the form completely and submit it to the Wisconsin TB Program by **fax (608) 266-0049** or by **mail to: TB Program – Division of Public Health, PO Box 2659, Madison WI 53701-2659.**

Local Health Department Contacted (mm/dd/yyyy), Referral Source, Reported to LHD Within 24 Hrs Date the LHD is notified of the suspect (or case) by whom and was the suspect (or case) reported to the LHD within 24 hours of the patient being considered a suspect. Referral source is the person/agency who refers the suspect (or confirmed case) to the LHD.

Wisconsin Administrative Code HFS 145, Appendix A, includes **Tuberculosis** with Category I diseases of "urgent public health importance" that shall be reported **IMMEDIATELY** to the patient's local health officer **upon identification of a case or suspected case**. Once reported to the local health officer, the local health officer is required to notify the State Epidemiologist immediately [HFS 145.04 (4)]

Name of Patient, Date of Birth, Gender, Race, Patient Address and Telephone Number

Name of Local Health Department (LHD), Public Health Nurse, Telephone Number of PHN Put the name of the primary PHN contact and whichever phone number is better for contacting the PHN (LHD or PHN's direct number).

Date Reported to the State TB Program These fields assist in tracking whether reporting time frames are consistent with statutory reporting criteria (see above).

Name of Primary Physician, Telephone Number, Name of Other Physician (Pulmonary Specialist, etc.), Telephone Number

CHEST X-RAY: Record date(s), Results of X-ray, Location Date(s) and specific result(s). Use comment section for results that are not addressed by the boxes.

BACTERIOLOGY: Laboratory where specimen was sent
Indicate all laboratories where the specimens were sent for smear, Mycobacterium Tuberculosis Direct (MTD) / polymerase chain reaction (PCR) and culture results. There is often more than one laboratory involved.

Specimen information - Date Collected, Source, Smear (POS, NEG, Results), MTD/PCR and Culture
For smear results, indicate the amount of AFB seen on positive specimens (e.g. 1-9/field). MTD/PCR note any comments (such as inhibitors, specimen too old, etc.). On the culture, indicate the date the specimen was identified (either as TB or not TB).

Drug Sensitivities For each medication, indicate if the TB isolate is sensitive or resistant to the drug

TREATMENT: Date started (mm/dd/yyyy), DOT, regimen duration, Drugs, Dose(s) and Frequency
Indicate the date the patient began appropriate TB disease treatment, whether or not it was given as directly observed therapy (DOT), and if given via DOT, where DOT occurred (workplace, LHD, home, etc.). Record the initial medication regimen prescribed.

PATIENT HISTORY:
Date of PPD, Results Document current TB skin test (PPD) information in millimeters
Date of Previous PPD, Results Document last known (and documented) previous test date and results
If previously tested, list city and state Document where previous test was given.
If previous PPD was positive, was treatment for latent TB infection (LTBI) taken? If yes, was treatment completed?
Determine if patient with a previous positive skin test took treatment for LTBI and if LTBI treatment was completed.

Signs and Symptoms Indicate which symptoms the patient currently has or has had in relation to their TB suspect case status. Note the duration of the symptoms.

Patient history of TB disease?, Family history of TB disease? Fill in as indicated. Note: history of TB disease, not infection.

HIV status HIV information is requested under the authority of Wis. Stats. s. 250.04 (1). All client information is confidential under Wis. Stat.146.82 (1). Per Centers for Disease Control and Prevention (CDC) protocol all individuals with TB disease should be tested for HIV infection.

Other risk factors? Note other risk factors. If a patient is infected with TB, the risk of TB disease increases with corticosteroid use at high dose for long duration (e.g. >15 mg/day of prednisone (or equivalent) for 1 month or more).

Homeless in the past year? Non-injection drug use within the past year?, Injection drug use within the past year? Alcohol use within the past year? Regular, Excess, Smoker? Fill in per patient and medical history. Re. alcohol use: subjective assessment to guide DOT decision and the recommendations given to physician. ***Regular* alcohol use** indicates baseline and follow-up **liver function tests (LFTs) may be indicated** [2/day – men, 1/day – women]. ***Excess* alcohol use** is an indicator for **DOT** and **LFTs** are indicated to supplement frequent liver symptom monitoring. [Reports intake that exceeds *regular*; diagnosis, hospitalization or treatment for excess alcohol, etc.]

Foreign born?, Month and Year arrived in USA, Type of VISA Document the patient's country of origin and both the **month and year** of their arrival in the USA. Indicate which type of VISA they came on.

Recent foreign travel?, Resident of long-term care or correctional facility? Disposition Fill in as indicated.

Tuberculosis Reporting Made Simple

(or The A-F-B's of TB Reporting - 2001)

How do I submit a report and how quickly must it be submitted?

HFS 145, Appendix A, divides the reportable communicable diseases into three categories. **Tuberculosis** is included with Category I diseases of "urgent public health importance" that "shall be reported **IMMEDIATELY** to the patient's local health officer **upon identification of a case or suspected case**." In addition to the immediate report (phone or fax) complete and mail or fax an Acute and Communicable Diseases Case Report (DPH 4151) **within 24 hours**. Health care providers report to the local health department; health departments report to the state TB Program/epidemiologist. One complete, accurate 4151 is all that is needed.

Nontuberculous mycobacterial disease is included in Category II which are diseases that "shall be reported to the local health officer on an Acute and Communicable Disease Case Report (DPH 4151) or by other means **within 72 hours** of the identification of a case or suspected case."

Does extrapulmonary tuberculosis (tuberculosis in any other part of the body other than the lungs) need to be reported within the same time frames?

YES.

How do I know someone is a TB "suspect?"

The TB Program, Wisconsin Division of Public Health uses the following criteria to indicate "suspect" status:

1) Clinical signs and symptoms that suggest TB is *definitely suspected* by a health care provider, generally documented as a suspicion in the patient's medical record (e.g. chest x-ray impression states "probable TB.") This does not include every person who has "rule out" TB as a differential diagnosis just because they have a cough and the physician has ordered a skin test.

OR

2) AFB positive smears where there is no previous laboratory report of non-tuberculous mycobacteria

OR

3) Health care provider's suspicion of TB as indicated by written prescription of at least 2 anti-tuberculous medications for a period of more than 2 months. (The two drug regimen, Rifampin and Pyrazinamide for 2 months to treat TB infection does *not* apply to this criteria.)

What if a specimen was smear negative, but the culture is positive for a not-yet-identified mycobacteria? (Smear negative, culture positive for AFB, identification pending)

If the patient meets at least **one** of the above criteria for a TB **suspect**--**report**.

If the patient does not meet the above criteria, and if identification of the AFB is imminent (i.e.: identification will be complete in-house or at a reference laboratory within the week) report according to requirements **after identification** is known.

If the patient does not meet the above criteria, but identification is expected to be delayed (e.g.: reference laboratory is located out of state), **report** as a TB **suspect**. (Correct later if TB is ruled out.)

Tuberculosis Reporting Made Simple

(or The A-F-B's of TB reporting - 2001)

Legal background:

Excerpts from:
DEPARTMENT OF HEALTH AND FAMILY SERVICES
Chapter HFS 145

CONTROL OF COMMUNICABLE DISEASES

HFS 145.03 Definitions. In this chapter:

(1) "Case" means a person determined to have a particular communicable disease on the basis of clinical or laboratory criteria or both.

(15) "Suspected case" means a person thought to have a particular communicable disease on the basis of clinical or laboratory criteria or both.

HFS 145.04 Reports of communicable diseases. **(1)** RESPONSIBILITY FOR REPORTING. (a) Any person licensed under ch. 441 or 448, Stats., knowing of or in attendance on a case or suspected case shall notify the local health officer or, if required under Appendix A of this chapter, the state epidemiologist, in the manner prescribed in this section.
(b) Each laboratory shall report the identification or suspected identification of a disease–causing organism or laboratory findings indicating the presence of a communicable disease to the local health officer or, if required under Appendix A of this chapter, to the state epidemiologist.
(c) Each health care facility shall ensure that reports are made to the local health officer or, if required under Appendix A of this chapter, to the state epidemiologist, in the manner specified in sub. (3). When a case is identified or suspected in a health care facility having an organized program of infection control, the person in charge of the infection control program shall ensure that the case or suspected case is reported to the local health officer or, if required under Appendix A of this chapter, to the state epidemiologist, minimizing unnecessary duplication.

(3) URGENCY OF REPORTS. (a) A person, laboratory or health care facility required to report under sub. (1) shall report communicable diseases of urgent public health importance as listed in category I of Appendix A of this chapter to the local health officer immediately upon identification of a case or suspected case. If the local health officer is unavailable, the report shall be made immediately to the state epidemiologist.

(4) HANDLING OF REPORTS BY THE LOCAL HEALTH OFFICER. (a) The local health officer shall notify the state epidemiologist immediately of any cases or suspected cases reported under sub. (3) (a).

2. **Ordering medications** for persons who are: suspects, or confirmed cases of active tuberculosis; contacts to an active disease case and have a high-risk medical condition (such as HIV+, diabetes); a child age four or under; or a youth age five or older that a physician has placed on window prophylaxis. (See section 2. i. for complete criteria.)

    a. Supply the offices or clinics in your area with the most current DPH 4000 forms and instructions in advance so they are prepared to treat clients.

    b. Determine in advance which local pharmacies will be used to fill the prescriptions and establish availability of the tuberculosis medications and dosages. Whenever possible, honor client's preference for a pharmacy if the client already has an established pharmacy provider and if TB medications are available from that pharmacy.

    c. Facilitate a medical evaluation for the client. If the prescribing physician does not have the most current information on treating active disease, provide resources. Contact the WI TB Program if the physician could benefit from a consultation with the WI TB Program medical consultant for medical decision making or if you have any questions.

    d. Fax the blank DPH 4000 to the physician if necessary and provide any needed instructions to the physician and/or the office staff. Medication protocols approved by the American Thoracic Society, (ATS/CDC/WI TB Program) are printed directly on page two of the DPH 4000 form including the dosage forms in which the medications are manufactured. Pages three and four provide instructions.

    e. Review in advance what would be an expected ATS/CDC/WI TB Program approved medication regimen for this client, including calculating the dosage based on the person's weight and the dosage forms of tablets that are available.

    f. Obtain physician's prescriptions for initiating medication therapy appropriate for the client and take the following actions:

        1. Compare the regimen prescribed by the physician to the approved regimens and note any variations or complications.

        2. Use the information on DPH 4000, Wisconsin Antituberculosis Therapy Program Initial Request for Medication, especially page two and address any discrepancies.

        3. Contact the physician after reviewing the prescriptions if you need more information about his/her rationale for the prescription based upon your comparison of the prescriptions to the approved regimens and resolve prescription/treatment issues with physician and client.

        4. Phone the TB Program at 608-266-9692 with any questions.

    g. Complete the data elements for the client on DPH 4000, **including current weight**, according to instructions on pages three and four accompanying the document. Do not delay sending it if some <u>non-critical</u> information is incomplete or pending.

h. Fax **page one** of the **completed** form DPH 4000 with the signed physician's prescriptions on it to the WI TB Program (Fax # - 608-266-0049) and alert the TB Program staff by phone that you are sending a priority request. There is no need for you to fax pages 2, 3 or 4 of the instructions back to the TB Program.

1. Fax copies of the physician's prescriptions (at the same time, properly identified) along with page one of the DPH 4000 form if physician did not prescribe on the DPH 4000 form. A fax of an original signature is equivalent to an original signature.

2. Alert the WI TB Program by phone that you have a request that needs evaluation on a priority basis. Same day approval is done when the TB Program is alerted, however, payment authorization may take 24 to 72 hours from the time the DPH 4000 form is received by the TB Program during weekend or holiday periods.

3. Receive authorization for payment for these drugs by fax and/or phone call. [***Fewer missing items expedite the process; missing items delay the process***.]

SPECIAL CIRCUMSTANCES THAT ARE APPROVED FOR LOCAL PHARMACY FILLING:

i. Order medications locally using the same procedure used for active disease clients for persons needing treatment for TB infection or window prophylaxis because the person meets these criteria:

1. A **close contact** to an active case with a newly positive TB skin test who also has a high risk *medical* condition (but active disease has been ruled out).

2. A contact to a case who is a young child or is HIV+ or has another high-risk medical condition that results in them being immunosuppressed, regardless of their skin test results at the initial test (e.g. even if they test "negative).

3. A contact who is age five or over but a physician specialized in the treatment of children with tuberculosis has made a medical determination that window prophylaxis is indicated (e.g. even if the initial skin test is negative).

Treatment of a person with LTBI who is not at high-risk because of age or a medical condition is not an emergency in most instances and drugs will be sent from the TB Program central contract pharmacy. Population risk factors do not apply. Rationale: being born in a country where TB is prevalent increases the risk of having contracted TB; but if a person has no medical risk factors and is not a child age four and under, once active disease has been ruled out, treatment for LTBI does not need to be immediate.

j. Receive fax from the TB Program that provides a client identification (ID) number to authorize pharmacy billing and TB Program payment for the medications. The WI TB Program checks to see if the person is a Medical Assistant recipient and completes the Antituberculosis Therapy Authorization sheet before faxing it to the local health department.

k. Supply the local pharmacy with the original **prescriptions** so they can dispense the medications for the client. Provide them with the **Antituberculosis Therapy Authorization** with the **Client ID Number** and the **billing instructions** provided by the WI TB Program. Instruct the pharmacy in the correct direct billing procedures and answer their questions.

3. **Receiving and picking up medications**

a. Go to the pharmacy and pick up the medications dispensed for the client by the pharmacy, acting as an agent of the patient. Facilitate communication by phone between client and pharmacist if there are questions or issues the pharmacist or client would like to discuss.

> "Drugs necessary for the treatment of Mycobacterium tuberculosis shall be purchased by the Wisconsin Department of Health and Family Services…and dispensed to patients through the public health dispensaries, local health departments, physicians or advanced practice nurse prescribers." Ch. s. 252.10(7), Wisconsin Statutes

b. Follow local health department policies, procedures and practices regarding medication delivery and storage for all tuberculosis medications in the health department, for both active disease and LTBI. See section B. of procedure/guideline specific to TB medications in the health department.

4. **Initiating care and services**

a. Visit the client for assessment and to initiate case management according to health department policies, procedures and practices.

b. Deliver the medications that have been dispensed by the pharmacy for that client and establish DOT (Directly Observed Therapy) according to related health department policies, procedures and practices. (Refer to *Tuberculosis Nursing: A Comprehensive Guide to Patient Care*, p. 47-48.)

c. Educate the client and family regarding tuberculosis, importance of adherence and completion of therapy. Use incentives with the client that will ensure adherence to therapy. [The American Lung Association of Wisconsin (ALA/W) administers the incentive program that is funded by the WI TB Program]

> *It is the statutory responsibility of the health department to protect the health of the public by ensuring completion of tuberculosis treatment. This means the role of the health department staff with a tuberculosis client must have an assertive component in addition to the caring, supportive relationship the health department provides for all clients. Public health staff must achieve client adherence to tuberculosis therapy to protect the health of the public now and for future generations.*

d. Assess all clients pre-treatment and re-assess them through out treatment for DOT (Directly Observed Therapy). Prioritize, if necessary, based on defined criteria. DOT is the standard of care in the health department for treatment of tuberculosis disease clients and all suspects until active disease is ruled out and may be necessary for LTBI clients as well. (See section of procedure on LTBI treatment and national and CDC resources and refer to *Tuberculosis Nursing: A Comprehensive Guide to Patient Care*, p. 77-83.)

e. Assess all clients pre-treatment and throughout therapy for

- risk factors for adverse reactions,
- occurrence of adverse reactions,
- medication efficacy,
- side effects,
- adherence to regimen and
- overall effect of treatment on the person and family (incl. cultural and psychosocial issues.)

f. Problem-solve pro-actively and correct any issues that occur according to case management practice.

g. Collaborate with the staff, infection control practitioner and/or discharge planner for the case or suspect who is hospitalized or is a resident in a nursing home to ensure monitoring of condition and referral to the health department prior to discharge.

h. Ensure that there will be no interruption in therapy after institutional discharge. In addition to coordinating with discharge planning services, coordinate with the prescribing physician and the pharmacy if there are any changes in physician or pharmacy so that therapy is not interrupted.

i. **Arrange for medication refills throughout therapy through the local pharmacy for clients with active disease or those clients listed in section "i." who begin medications with the local pharmacy.** Once the WI TB Program has authorized payment for the client's prescriptions, any pharmacy can bill the program for the medications for that client. Authorization to bill the TB Program can be transferred to any Wisconsin pharmacy. For border-state pharmacies, call the TB Program to make easy arrangements for them to also bill the WI TB Program. Medication refills for clients with active tuberculosis disease are always obtained directly from the local pharmacy throughout therapy. Medications for TB infection clients who are not high-risk contacts or on window prophylaxis are sent to the health department through the WI TB Program from the central contract pharmacy.

j. Inform the WI TB Program of **any** changes in the client's medication regimen. This can be accomplished by phone or fax and is needed to ensure medication reimbursement.

k. Inform the WI TB Program of any changes in the client's Medicaid status during therapy by phone or fax. (e.g., after the initial prescription for which the WI TB Program is billed, client becomes eligible for Medicaid. Once they are Medicaid eligible, the Medicaid is their primary payor.)

5. **Closing out** a suspect of active disease after active disease is ruled out

a. Notify the WI TB Program by phone when a suspect of active disease is confirmed as not having TB disease, including those who will receive treatment for infection. For suspects who are found not to have disease *or* infection the WI TB Program may request that the health department submit a copy of some information that resolves what happened with the person but there is no required documentation that must be submitted. (e.g. the person did not have tuberculosis, but did have *M. avium.* Sometimes questions come up later.)

b. Continue the procedure for treating persons with LTBI for the suspect who turns out to have infection. Submit the 4125 (Follow Up on Therapy) when this person has completed therapy, transferred out of state, etc., according to section of the procedure on LTBI treatment.

c. Continue implementation of the procedures for medications, services, DOT, case management, etc. for the person with active disease until therapy is complete or care is transferred to another health department (see section 6. on transfers).

6. **Notify the WI TB Program by phone when the person with active disease has completed therapy, moved out of state, expired, etc.** (See sections in procedure below for instate, interstate and international notification for **transfers** of persons who continue on therapy for active disease or LTBI after they are no longer cared for by the local health department.)

   a. Close client's record according to health department policies, procedures and practices, but do not delay reporting the following information to the WI TB Program while waiting for an opportunity to close out the entire record.

   b. Documentation of **sputum culture conversion** according to the following criteria:

      1. Sputum culture conversion is only indicated for patients who had one or more positive cultures **from sputum** and later had one or more negative cultures documented.

      2. Sputum culture conversion does **not** apply to patients who had positive cultures from other pulmonary specimens *without* positive sputum cultures –e.g. **bronchoscopy fluid**.

      3. Completion of an appropriate drug treatment regimen is considered adequate closure documentation for a case of active respiratory tuberculosis that is diagnosed by specimens other than sputum cultures. (A bronchoscopy that is not clinically indicated is not required to document "culture conversion.")

   c. Collection date of initial positive sputum culture

   d. Collection date of first consecutively negative sputum culture according to the following criteria

      1. This date should be at least one week after the last positive sputum culture was obtained and

      2. Any subsequent sputum cultures must also be negative.

      3. Any positive sputum cultures after this date means culture conversion has *not* occurred and

      4. Further *negative* specimens are needed.

   e. Date and results of the follow-up chest x-ray – must be more than two months after drug treatment was initiated

   f. Date therapy stopped

g. Reason therapy stopped (includes therapy was completed)

h. Number of weeks and site of DOT for patients having DOT

7. Notify the WITBP by phone (608-266-9692) as soon as you learn that any person with active TB or LTBI is moving out of your jurisdiction.

   a. Report the following information:

      - Client's new address and phone number
      - The date the person is relocating
      - Any medication needs prior to client's move

   b. Receive name, address and phone number of the appropriate health department for that address from WI TB Program. (This may take longer for out of state, and international transfers.)

   c. Refer client for continuing care using the steps below after the WI TB Program has located the appropriate health department.

   d. Gather relevant documentation to forward to the new health department such as

      1. Culture results
      2. Physician's notes
      3. Chest x-ray impression, skin test dates and results in mm.
      4. Sensitivity results, LFT results, etc.

   e. Write a summary letter to mail or fax to the new health department along with the documentation above that includes at least the following:

      1. Demographic data and any "tips" that may be needed to locate the person
      2. Things that work well for the person like timing, incentives used, etc.
      3. Information about treatment adherence, cultural, family and psychosocial issues,
      4. Side effects or adverse reactions; what has worked well, not well,
      5. Follow-up medical appointments, etc.

   f. Phone the new local health department and provide (mail/fax) referral information regarding the client, case manager to case manager if possible.

   g. Handle medications that have not yet been administered or delivered according to the following criteria:

      1. Within the state of Wisconsin:

      - Patient may take the bottle they are currently using.
      - Send any undelivered bottles to the receiving health department as an agent of the patient (***only* in WI**).
      - Ensure that patient is supplied with adequate medications to avoid interruption of therapy and that the *receiving* health department is alerted about what bottles you are sending and when

refills need to be ordered so that therapy is not interrupted.

2. To other states and to international locations:

- Patient may take the bottle they are currently using *and one additional bottle*.
- Do *not* send any medications out of Wisconsin.
- Ensure that patient is supplied with adequate medications to avoid interruption of therapy and that the *receiving* health department is alerted to order refills promptly so that therapy is not interrupted.

4. Document medication handling accordingly in client's record and/or health department TB Drug Inventory log.

5. Provide the appropriate supply and instructions to the patient who is managing their own medications.

6. Develop an alternative arrangement with the receiving health department if client has difficulty handling their own medications.

h. Provide the patient a copy of the information provided to the new health department and the contact information for the new health department with complete instructions.

i. Instruct the patient to make contact with the new health department upon arrival and provide him/her with the phone number and address of the health department.

j. Provide the WI TB Program with information/documentation according to the following criteria:

1. For persons moving **within Wisconsin**, **phone notification** is all that is needed by the WI TB Program. For the receiving health department, **call** the new case manager and **forward** all pertinent information/documentation to the receiving health department as indicated. Retain copies for your health department records.

2. For persons moving **out of state**, phone the WI TB Program to facilitate smooth transition and use the following criteria:

Persons with active disease-

- Request that the WI TB Program do an interstate transfer. [The interstate transfer information is completed on a CDC form by the WI TB Program, (interstate notification form) but the primary ***clinical communication to the receiving health department must be done by the health department*** that is sending the patient information.]

- Send a copy of the summary letter addressed to the receiving health department **to the WI TB Program.** (keep a copy for your records)

- Provide any missing information to the receiving health department and to the WI TB Program if it was not previously reported. [*WI TB Program forwards a copy of a CDC form, Report of Verified case of Tuberculosis (RVCT) to the receiving health department. Missing data*

may be harder to find later if questions come up, complete information at the time of transfer may save re-work.]

Persons with LTBI –

- Follow identical process for persons with active disease related to medication handling, calling and sending or faxing the clinical information on the client and

- Complete and submit a DOH 4125, Follow Up on Therapy form to the WI TB Program. (WI TB Program sends the receiving state's TB Program a copy of the patient's DOH 4000 form and a CDC Interstate Tuberculosis Notification document with the patient's new address to compliment the clinical information you sent to the receiving local health department.)

3. Phone the WI TB Program for guidance when referring persons with active disease or LTBI for continuing care if they are **migrating from state to state within the United States or to and from Mexico** (most commonly for work) as the process of notification for these individuals is unique.

4. For persons **moving out of the United States**, with either active disease or LTBI, phone the WI TB Program to facilitate smooth transition and use the following criteria:

   Persons *moving* to Mexico –

   - Phone the WI TB Program for specific instructions as the international notification process for Mexico is unique only to Mexico.

   Persons with active disease-

   a. Recognize that the international transfer process is the least effective transfer process, therefore **ensure that the patient is well informed about the need to follow-up in their new country** and **takes** a copy of their medical records with them.

   b. Notify the WI TB Program promptly by phone and write a summary letter of the patient's clinical information "To Whom it May Concern" as the actual health department name and address is generally not known.

   c. Send the summary letter (keep a copy for your records) to the WI TB Program who will send it, along with a CDC International Tuberculosis Notification document and the patient's Report of Verified Case of Tuberculosis (RVCT) to the receiving country. Provide the program with any information that may not have been reported so that the information sent to the receiving country is as complete as possible.

   Persons with LTBI -

   a. Recognize that countries outside the United States often cannot make follow-up on persons with infection a priority as they must concentrate the resources they have on a large number of cases with active disease. Clients must leave the U.S. well equipped

with knowledge, full clinical record copies and motivation to follow-up on their own.

b. Handle medications and gather information as with all transfers and address your summary letter “To Whom it May Concern” just as done with international transfers of active disease cases.

c. Give the patient a copy of all the information to take with him/her and ensure understanding of the importance of follow-up in the new country.

d. Complete and submit DOH form 4125 (Follow-up on Therapy) to the TB program documenting the international transfer.

DEPARTMENT OF HEALTH & FAMILY SERVICES
Division of Public Health
DPH 4000 (Rev. 07/00)

STATE OF WISCONSIN
s. 252.10 (7), Wis. Stats.
(608) 266-9692
FAX: (608) 266-0049

WISCONSIN ANTITUBERCULOSIS THERAPY PROGRAM
INITIAL REQUEST FOR MEDICATION

Information for completing form on reverse side. Instructions on separate page.

Patient Name (Last, First, Middle Initial)			Date of Birth (mm/dd/yyyy)
Address (Street or Rural Route)			Telephone Number ( )
City	Zip Code	County	Patient's Medicaid ID No.(If applicable)
Sex	Race	Weight	Parent / Guardian Name (If Patient is under 18 years of age)

Physician Name	Physician DEA Number
Address(Street, City, State, Zipcode)	Telephone Number ( )

1. Mantoux Tuberculin Skin Test: Date Applied _____ Date Read _____ Results **(induration only)** _____ mm

1. Reason for skin test and referral for treatment: (refer to instructions for explanation)

☐ Treatment for active TB disease (suspected or confirmed)

☐ Contact to a current case of TB Name of case, if known _____

☐ Medical risk factor Specify _____
(e.g. diabetes, immunosuppression, substance abuse, skin test conversion, etc.)

☐ Population risk factor Specify _____
(e.g. health care worker, correctional facility, foreign-born, nursing home, etc.)

3. Chest X-Ray: Date _____ Results: ☐ Normal ☐ Abnormal ☐ Abnormal but stable
(If Abnormal, or Abnormal but stable, include copy of chest x-ray report)

Check all that apply

4. ☐ Prior Mantoux tuberculin skin test? Specify Date:_____ Results_____mm

5. ☐ Risk factors for adverse reactions or non-adherence? Specify_____

Baseline blood tests, if applicable* Date_____ Type of tests _____
*Please refer to references, listed on reverse, for explanation of patient monitoring requirements.

6. ☐ Prior treatment for tuberculosis infection or disease? Explain:_____

7. ☐ Born outside the United States? Please specify country of birth_____ Arrival in U.S. (mm/yyyy) _____

Review treatment recommendations / dosages on reverse side

Drug Selection	Dosage	Number of Months
Isoniazid (INH)	_____	_____
Rifampin (RIF)	_____	_____
Pyrazinamide (PZA)	_____	_____
Ethambutol (EMB)	_____	_____
Other (please specify)	_____	_____

For Division of Public Health Use Only

Patient No._____

Sent to_____

_____

_____

SIGNATURE - Physician_____ Date Prescription Ordered _____

Submit completed form to: Local Health Department or
Division of Public Health, Wisconsin TB Program, P.O. Box 2659, Madison, WI 53701-2659

Recommended Drug Regimens for Treatment of Active Tuberculosis in Adults and Children

	Induction Phase	Continuation Phase
Option 1--Pulmonary and extrapulmonary TB in adults and children	Daily isoniazid, rifampin, and pyrazinamide* with ethambutol or streptomycin* for 8 wk. Discontinue ethambutol or streptomycin when susceptibility to isoniazid and rifampin is demonstrated.	Daily or 2-3 times/wk† isoniazid and rifampin (by DOT) for 16 wk.?
Option 2--Pulmonary and extrapulmonary TB in adults and children	Daily isoniazid, rifampin, and pyrazinamide* with ethambutol or streptomycin* for 2 wk then 2 times/wk† for 6 wk (by DOT).	2 times/wk† isoniazid and rifampin (by DOT) for 16 wk.?
Option 3--Pulmonary and extrapulmonary TB in adults and children	Treat by DOT, 3 times/wk† with isoniazid, rifampin, pyrazinamide*, and ethambutol or streptomycin* for 24 weeks.§	
Option 4--Smear- and culture-negative pulmonary TB in adults, latent TB infection (LTBI) in adults with a chest film suggesting old healed tuberculosis, or LTBI in adults with silicosis who are sputum smear- and culture-negative.	Daily isoniazid and rifampin, preferably with pyrazinamide* for 8 wk.	Daily or 2 times/wk† (DOT) or 3 times/wk† (DOT) isoniazid and rifampin for 8 wk.?
Option 5--Pulmonary and extrapulmonary TB in adults and children when PZA is contraindicated	Daily isoniazid and rifampin for 36 weeks?, with ethambutol or streptomycin until susceptibility to isoniazid and rifampin is demonstrated.	

*Avoid streptomycin and pyrazinamide for pregnant women.

†All regimens administered 2 times/wk or 3 times/wk should be monitored by directly observed therapy (DOT) for the duration of therapy.

? For infants and children with miliary TB, bone and joint TB, or TB meningitis, treatment should last at least 12 months. For adults with these forms of extrapulmonary TB, response to therapy should be monitored closely and treatment prolonged as judged on a case-by-case basis.

§The strongest evidence from clinical trials is the effectiveness of all four drugs administered for the full 6 months.

Recommended Drug Regimens for Treatment of Latent Tuberculosis Infection (LTBI) in Adults

Drug	Interval and Duration	Comments	Rating* HIV -	Rating* HIV +
Isoniazid	Daily for 9 mo†§	In HIV-infected patients, isoniazid may be administered concurrently with NRTIs, protease inhibitors, or NNRTIs	A	A
	Twice weekly for 9 mo†§	Directly observed therapy (DOT) must be must be used with twice-weekly dosing	B	B
	Daily for 6 mo§	Not indicated for HIV-infected persons, those with fibrotic lesions on chest radiographs, or children	B	C
	Twice weekly for 6 mo§	DOT must be used with twice-weekly dosing	B	C
Rifampin plus pyrazinamide	Daily for 2 mo	May also be offered to persons who are contacts of patients with isoniazid-resistant, rifampin-susceptible TB	B	A
		In HIV-infected patients, protease inhibitors or NNRTIs should generally not be administered concurrently with rifampin; rifabutin can be used as an alternative for patients treated with indinavir, nelfinavir, amprenivir, ritonavir, or efavirenz, and possibly with nevirapine or soft-gel saquinavir▲		
	Twice weekly for 2-3 mo	DOT must be used with twice-weekly dosing	C	C
Rifampin	Daily for 4 mo	For persons who cannot tolerate pyrazinamide	B	B
		For persons who are contacts of patients with isoniazid-resistant, rifampin-susceptible TB who cannot tolerate pyrazinamide		

* Strength of recommendation: A = preferred; B = acceptable alternative; C = offer when A and B cannot be given.

†Recommended regimen for children younger than 18 yr of age.

§ Recommended regimens for pregnant women. Some experts would use rifampin and pyrazinamide for 2 mo as an alternative regimen in HIV-infected pregnant women, although pyrazinamide should be avoided during the first trimester.

▲Rifabutin should not be used with ritonavir, hard-gel saquinavir, or delavirdine. When used with other protease inhibitors or NNRTIs, dose adjustment of rifabutin may be required.

Dosage Recommendations

Drugs (Dosage Form)	Dosage: Daily Children*	Daily Adults	Two Times per Week Children*	Two Times per Week Adults	Three Times per Week Children*	Three Times per Week Adults
Isoniazid (100 or 300 mg tablets)	10-20 mg/kg Max. 300 mg	5 mg/kg Max. 300 mg	20-40 mg/kg Max. 900 mg	15 mg/kg Max. 900 mg	20-40 mg/kg Max. 900 mg	15 mg/kg Max. 900 mg
Rifampin (150 or 300 mg capsules)	10-20 mg/kg Max. 600 mg	10 mg/kg Max. 600 mg	10-20 mg/kg Max. 600 mg	10 mg/kg Max. 600 mg	10-20 mg/kg Max. 600 mg	10 mg/kg Max. 600 mg
Pyrazinamide (500 mg tablets)	15-20 mg/kg Max. 2 g	15-30 mg/kg Max. 2 g	50-70 mg/kg Max. 4 g	50-70 mg/kg Max. 4 g	50-70 mg/kg Max. 3 gm	50-70 mg/kg Max. 3 g
Ethambutol† (100 or 400 mg tablets)	15-25 mg/kg Max. 2.5 g	15-25 mg/kg Max. 2.5 g	50 mg/kg -	50 mg/kg -	25-30 mg/kg -	25-30 mg/kg -
Streptomycin (injection)	20-40 mg/kg Max. 1 g	15 mg/kg Max. 1 g	25-30 mg/kg Max. 1.5 g	25-30 mg/kg Max. 1.5 g	25-30 mg/kg Max. 1.5 g	25-30 mg/kg Max. 1.5 gm

Combination drug dosing§

Rifamate® (150 mg isoniazid and 300 mg of rifampin in one tablet)	The usual adult dose is two capsules daily, taken at the same time.		
Rifater® (50 mg isoniazid, 120 mg of rifampin, 300 mg of pyrazinamide in one tablet)	Up to 98 lb., or 44 kg 4 tablets daily to be taken together	99-120 lb., or 45-54 kg 5 tablets daily to be taken together	121+ lb., or 55+ kg 6 tablets daily to be taken together

*Children ≤12 years of age.

†Ethambutol is generally not recommended for children whose visual acuity cannot be monitored (children <8 years of age). However, ethambutol should be considered for all children with organisms resistant to other drugs, if susceptibility to ethambutol has been demonstrated or susceptibility is likely.

§Adapted from materials produced by Bureau of Tuberculosis Control, New York City Department of Health.

References

Treatment of tuberculosis and tuberculosis infection in adults and children. *Am. J. Respir. Crit. Care Med.* 1994;149:1359-1374.

Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am. J. Respir. Crit. Care Med.* 2000;161:S221-S247

Instructions for completing ANTITUBERCULOSIS THERAPY PROGRAM Initial Request for Medication

This form authorizes the purchase of anti-tuberculous medication through the Wisconsin Tuberculosis Program. The medication will be provided to any individual in Wisconsin with evidence of TB infection, TB disease, or close household contact to a person with infectious tuberculosis. Medication must be prescribed in accordance with guidelines published by the Centers for Disease Control, the American Thoracic Society, and the American Academy of Pediatrics.

Personally identifiable information on this form is voluntary however, incomplete information will result in rejection of the medication request. Information below marked with an * is necessary to complete the medication request.

***Patient Name, Date of Birth, Address, City, State, Zip, County** Include apartment number if appropriate. These fields are required in order to supply the medication to the correct patient through the appropriate local health department.

Telephone This field is not required, but will aid the local health department in contacting the patient.

Sex This field is required.

Race This field is not required but can aid in identifying trends in TB infection and disease.

* **Weight** This field is required as proper dosing is calculated using the mg/kg ratios established for standard dosing. Information about the patient's weight is especially important when the patient is a child.

Parent/Guardian Name Required for children less than 18 years of age.

* **Physician Name/Address/ Telephone** This field is required.

***Physician Drug Enforcement Agency (DEA) Number** This field is required.

Medicaid ID Number Please provide if patient is a Medicaid recipient.

1. **Mantoux Tuberculin Skin Test**: Dates and skin test measurement (in millimeters) are required. Measure only the transverse diameter of induration (palpable swelling) across the forearm (perpendicular to the long axis). Do not record as just "positive" or "negative." If there is no documentation of a skin test, but the patient self-reports a past positive, it will be necessary to repeat the test and record the current measurement

Criteria for tuberculin positivity, by risk group

Reaction ≥5 mm of induration	Reaction ≥10 mm of induration	Reaction ≥15 mm of induration
Human immunodeficiency virus (HIV)-positive persons	Immigrants from high prevalence countries	Persons with no risk factors for TB
Recent contacts of tuberculosis (TB) case patients	Injection drug users	
Fibrotic changes on chest radiograph consistent with prior TB	Residents and employees† of high-risk congregate settings	
Patients with organ transplants and other immunosuppressed patients (receiving the equivalent of ≥15 mg/d of prednisone for 1 mo or more§.)	Children younger than 4 yr of age or infants, children, and adolescents exposed to adults at high risk	
	Persons with clinical conditions that place them at high risk	
	Mycobacteriology laboratory personnel	

§ Risk of TB in patients treated with corticosteroids increases with higher dose and longer duration.
† For persons who are otherwise at low risk and are tested at the start of employment, a reaction of ≥15 mm induration is considered positive.

2. ***Reason for Skin Test and referral for treatment**: Please specify whether medication is ordered to treat suspect or confirmed active tuberculosis disease, exposure to a current case of infectious tuberculosis, infection in a person with medical risk factors or population risk factors, or other reason. **Contact to a case** means exposure within the past year to an individual with a confirmed or suspected case of infectious tuberculosis. Please include the name of the case, if known.

Medical risk factors include medical conditions predisposing a patient to TB disease (e.g. diabetes, immunosuppressive condition, intravenous drug abuse, etc.). *Refer to more complete list below.* **Population risk factors** include demographics that predispose a patient to TB exposure or infection (e.g. employment or residence in a health care facility, correctional institution, homeless shelter, foreign-born from a country with high TB prevalence, etc.). *Refer to more complete list below.*

Medical Risk Factors	**Population Risk Factors**
HIV infection	Residency or occupation in high-risk congregate settings:
Tuberculin skin test conversion	Prisons and jails
Fibrotic lesions (on chest X-ray) consistent with old, healed TB	Health care facilities
Injection drug use	Nursing homes and long-term care facilities
Diabetes mellitus	Shelters for homeless persons
Immunosuppressive therapy	Birth in a country having a high TB prevalence/incidence:
Chronic renal failure	Immigrants
Hematologic disorders, such as leukemia or lymphoma	Refugees
Malignant neoplasms, such as carcinoma of the heard or neck	Students
Weight at least 10% less than ideal body weight	Some migrant workers
Pulmonary silicosis	Socioeconomic predictors of exposure:
Gastrectomy or jejunoileal bypass	Low income
Age ≤ 5 years	Inner-city residence
	Migrant labor

3. * **Chest X-Ray**: Dates and results of current chest x-ray **(within past 6 months)** are required. **If the chest x-ray was abnormal or abnormal but stable, please submit a copy of the chest x-ray report with the medication request.**

4. **Prior Mantoux tuberculin skin test?** This information is important for patients who are part of a tuberculosis surveillance program (e.g., health care workers, correctional employees or inmates, etc.) in order to determine if the positive test is a recent skin test conversion.

5. **Are there any risk factors for adverse reactions or non-adherence which should be noted?** Please include any factors that may increase the patient's risk for adverse reactions or therapy non-adherence.

6. **Prior tuberculosis infection/disease?** This information will identify patients who may have received prior therapy and be at increased risk for drug resistance.

7. **Born outside the United States?** This field is not required but can aid in identifying trends in TB infection and disease.

* **Drug Selection**

Please specify which drugs with the prescribed dosage and duration. The dosage recommendations are listed on the back of the form. Keep in mind that the drugs come in the following formulations

Isoniazid	100 or 300 mg tablets
Rifampin	150 or 300 mg capsules
Pyrazinamide	500mg tablets
Ethambutol	100 or 400 mg tablets
Streptomycin	injection
Rifater®	50 mg isoniazid, 120 mg of rifampin, 300 mg of pyrazinamide in one tablet
Rifamate	150 mg isoniazid and 300 mg of rifampin in one tablet

References

Treatment of tuberculosis and tuberculosis infection in adults and children. *Am. J. Respir. Crit. Care Med.* 1994;149:1359-1374.

Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am. J. Respir. Crit. Care Med.* 2000;161:S221-S247.

Antituberculosis Therapy Authorization

Client Name: _____ Client ID: _____

Client Does Does Not have Medicaid*.

*For clients with Medicaid, the Client ID number is the same as the Medicaid number.

Attention Pharmacist:

The Wisconsin Antituberculosis Therapy Program is administered by the Tuberculosis Program of the Division of Public Health, Department of Health and Family Services. This patient is approved to receive medication through this program. You may request payment according to billing instructions. For clients with Medicaid, please bill Medicaid first.

If you do not have a copy of the billing instructions or have questions regarding the Wisconsin Antituberculosis Medication Program, call the Tuberculosis Program: 608-266-9692.

WISCONSIN TUBERCULOSIS DRUG REIMBURSEMENT PROGRAM (TBDRP)
BILLING INSTRUCTIONS

An invoice should be completed by the pharmacist and signed by both the pharmacist and the customer/patient representative (signature can also be on signature log rather than on each invoice). Claims should be submitted monthly, and payments by the TBDRP will be made directly to the pharmacy. The TBDRP covers the following anti-tuberculous medications: **isoniazid (INH), rifampin (Rifadin, Rimactane), pyrazinamide (PZA), and ethambutol (Myambutol)** including the following combination drugs: **Rifater and Rifamate,** as well as second line anti-tuberculosis drugs for the drug resistant tuberculosis including: **kanamycin (Kantrex), capreomycin (Capastat), ethionamide (Trecator-SC), cycloserine (Seromycin), ciprofloxacin (Cipro), ofloxacin (Floxin), levofloxacin (Levaquin), amikacin, and para-aminosalicylic acid (PAS).**

The invoice must include the information indicated below or your claims may be returned for further information, resulting in a delay of your payment.

1. **Pharmacy Name, Street Address, City, State, ZIP**

2. **Pharmacy FEIN Number** The federal employer identification number is needed to ensure payment to the appropriate agency.

3. **Client ID Number** The client ID is indicated on the Antituberculosis Therapy Authorization form.

4. **Client's Name**

5. **Date Rx(s) Filled**

6. **Product Name**

7. **Metric quantity** Number of pills dispensed.

8. **Days of Supply** A one-month or 30 day supply is the maximum amount that should be supplied to a patient at one time.

9. **National Drug Code (Labeler No., Product No., & Pkg.)** Include all of the digits of the NDC Number (including 0's). Claim forms with incomplete numbers may be rejected.

10. **Ingredient Cost** Enter your usual and customary price for the drug. **Reimbursement is based upon the WMAP allowable rate.** A table listing the current reimbursement rates is on pages 3-4.

11. **Dispensing Fee** Enter current Medical Assistance professional fee.

12. **Tax** The State of Wisconsin is exempt from paying state sales tax.

13. **Total Price** Add Ingredient Cost to Dispensing Fee.

14. **Signature of pharmacist or employee**

15. **Other Third Party Coverage** The Wisconsin Medical Assistance Program (WMAP) also pays for all medications covered by the TBDRP. The WMAP must be billed first if the client has MA. If the pharmacy is aware that an individual has health insurance with prescription drug coverage, the pharmacy should bill insurance that portion for which the insurer is responsible. The TBDRP should be billed only for the amount (copay and/or deductible) that the pharmacy has been authorized by the TBDRP to bill. If you have benefit coordination questions, call the TBDRP at (608) 266-9692.

16. **Ded Amount** Include the amount already paid PER MEDICATION by the client's insurance or other source of medication coverage (e.g. Medicaid).

17. **Balance** Indicate amount for which you are billing the TBDRP.

SUBMISSION OF CLAIMS

If the client is eligible for MA or the pharmacy is aware of other insurance coverage while enrolled in the TBDRP, the pharmacy must bill them first. The TBDRP is the payer of last resort. Like the MA program, pharmacies may not bill clients for the difference between their usual and customary charges and the reimbursement rate they receive from the TBDRP.

Retain one copy of the completed invoice for your records and send one copy in an envelope marked "confidential" to:

TBDRP--Tuberculosis Program
Division of Public Health
P.O. Box 2659
Madison, WI 53701-2659

If you have any billing related or client eligibility questions, please contact Nancy Dupont at (608) 266-9692 or Tanya Oemig at (608) 261-6319. Your participation in the TBDRP is appreciated.

NDC #	DRUG	Pkg Qnty	Max Fee	Disp. Fee
00185435130	Isoniazid 100 mg Tablet	30 each	1.65	4.88
various	Isoniazid 100 mg Tablet	100 each	5.50	4.88
17236018003	Isoniazid 100 mg Tablet	300 each	16.50	4.88
Various	Isoniazid 100 mg Tablet	1000 each	55.00	4.88
Various	Isoniazid 300 mg Tablet	30 each	2.40	4.88
Various	Isoniazid 300 mg Tablet	35 each	2.80	4.88
Various	Isoniazid 300 mg Tablet	100 each	8.00	4.88
51079008324	Isoniazid 300 mg Tablet	300 each	24.00	4.88
Various	Isoniazid 300 mg Tablet	1000 each	80.00	4.88
46287000901	Isoniazid Syrup 50mg/5ml	473 ml	18.25	4.88
00068059701	Rifadin (rifampin) IV 600 mg vial	1 each	71.44	4.88
00068051030	Rifadin (rifampin) 150 mg Capsule	30 each	40.23	4.88
00068050830	Rifadin (rifampin) 300 mg Capsule	30 each	57.02	4.88
00068050860	Rifadin (rifampin) 300 mg Capsule	60 each	113.99	4.88
00068050861	Rifadin (rifampin) 300 mg Capsule	100 each	190.08	4.88
00185080130	Rifampin 150 mg Capsule	30 each	36.21	4.88
00185080101	Rifampin 150 mg Capsule	100 each	120.69	4.88
various	Rifampin 300 mg Capsule	60 each	102.59	4.88
various	Rifampin 300 mg Capsule	30 each	51.32	4.88
Various	Rifampin 300 mg Capsule	500 each	812.59	4.88
51079089020	Rifampin 300 mg Capsule	100 each	177.71	4.88
various	Rimactane (rifampin) 300 mg Capsule	100 each	173.99	4.88
00013530117	Mycobutin (rifabutin) 150 mg Capsule	100 each	468.58	4.88
51079069119	Pyrazinamide 500 mg Tablet	25 each	29.46	4.88
61748001209	Pyrazinamide 500 mg Tablet	90 each	91.29	4.88
various	Pyrazinamide 500 mg Tablet	100 each	106.38	4.88
various	Pyrazinamide 500 mg Tablet	500 each	487.79	4.88
61748001206	Pyrazinamide 500 mg Tablet	60 each	62.24	4.88
61748001209	Pyrazinamide 500 mg Tablet	90 each	91.29	4.88
Various	Myambutol (Ethambutol) 100 mg Tablet	100 each	53.40	4.88
Various	Myambutol (Ethambutol) 400 mg Tablet	100 each	178.65	4.88
00088057641	Rifater® (rifampin + isoniazid + pyrazinamide) Tablet	60 each	97.20	4.88
00068050960	Rifamate® (rifampin + isoniazid) Capsule	60 each	131.33	4.88
various	Kanamycin 1 G/3 ml Vial	3 ml	5.99	4.88
various	Kanamycin 500 mg/2 ml VI	2 ml	9.94	4.88
various	Kanamycin 75 mg/2 ml VI	2 ml	2.74	4.88
51479001801	Capastat (capreomycin) 1 G Vial	1 each	22.99	4.88
00008413001	Trecator-SC (ethionamide) 250 mg Tablet	100 each	230.70	4.88

NDC #	DRUG	Pkg Qnty	Max Fee	Disp. Fee
51479001901	Seromycin (cycloserine) 250 mg Pulvule	40 each	144.63	4.88
various	Cipro (ciprofloxacin) 250 mg Tablet	100 each	350.73	4.88
various	Cipro (ciprofloxacin) 500 mg Tablet	100 each	419.78	4.88
00026851448	Cipro (ciprofloxacin) 750 mg Tablet	100 each	419.78	4.88
00026851450	Cipro (ciprofloxacin) 750 mg Tablet	50 each	203.14	4.88
Various	Floxin (ofloxacin) 200 mg Tablet	50 each	186.09	4.88
Various	Floxin (ofloxacin) 200 mg Tablet	100 each	374.72	4.88
Various	Floxin (ofloxacin) 300 mg Tablet	50 each	221.45	4.88
Various	Floxin (ofloxacin) 300 mg Tablet	100 each	445.67	4.88
Various	Floxin (ofloxacin) 400 mg Tablet	100 each	470.08	4.88
00045152010	Levaquin (levofloxacin) 250 mg Tablet	100 each	662.20	4.88
00045152050	Levaquin (levofloxacin) 250 mg Tablet	50 each	328.80	4.88
00045152510	Levaquin (levofloxacin) 500 mg Tablet	100 each	772.68	4.88
00045152550	Levaquin (levofloxacin) 500 mg Tablet	50 each	384.03	4.88
00641235743	Amikacin 1 G/4 ml Vial	4 ml	16.88	4.88
00074195801	Amikacin 250 mg/ml Disp Syr	2 ml	30.00	4.88
various	Amikacin 250 mg/ml Vial	2 ml	8.44	4.88
various	Amikacin 250 mg/ml Vial	4 ml	16.88	4.88
various	Amikacin 250 mg/ml Vial	3 ml	12.66	4.88
Various	Amikacin 50 mg/ml Vial	2 ml	28.00	4.88

A. WI Tuberculosis Program – Communication, Services & Resources, con't.

➢ Persons with Latent Tuberculosis Infection (LTBI)

1. "Reporting" regarding tuberculosis infection – LTBI

a. Ensure that policies, procedures and practices are in place at the health department that ensure the collection of accurate information during the intake process. Persons who have a tuberculosis infection and are ***not*** at high risk for suddenly breaking down with disease are not ordinarily a threat to the health of the public. They are generally not infectious or contagious and do ***not*** need to be reported to public health. Reporting requirements apply only to tuberculosis suspects and active disease cases.

b. Ensure that a person who meets the definition of a ***suspect*** *is reported and cared for as a suspect* until active tuberculosis disease is ruled out, and that close and high-risk contacts receive window prophylaxis if indicated, according to the section of the procedure for treating disease.

c. Ensure that systems are in place to secure chest x-rays and medical evaluations for clients with positive skin tests so that active tuberculosis can be ruled out promptly. [Call the TB Program at 608-266-9692 if there are funding issues.]

d. Advocate for the client with the physician for treatment for LTBI when a person has been evaluated as a suspect and active disease has been ruled out. Merely stopping treatment for active disease without completion of treatment for infection could result in incomplete treatment. Medications for these clients can be obtained locally or through the WI TB Program. When the WI TB Program pays for the medication, public health involvement **is** required. Public health involvement is encouraged and preferred, however physicians are not prohibited from treating persons with LTBI on their own.

e. Notify the WI TB Program when a suspect has had TB ruled out and status is changed from suspect to infection. Faxing a new prescription for LTBI treatment, (DPH 4000 form may be used) along with the information as to how disease was ruled out is sufficient for notification. (See procedure below and instructions for completion of DPH 4000, especially data elements with asterisks. Inform the TB Program if medications are being obtained locally or are to be sent from the TB Program. Do not risk losing client to treatment and avoid interruption in therapy.)

2. **Initiating services** and ordering medications for a person with LTBI.

a. Supply the offices or clinics in your area with the current forms and instructions in advance so they are prepared to treat clients.

b. Determine in advance which local pharmacies will be used to fill prescriptions *when needed* and establish availability of tuberculosis medications and dosages. (Only for any unusual clients as described above who will not be getting their medications from the WI TB Program.)

c. Facilitate a medical evaluation and a physician's prescription for initiating medication therapy appropriate for the client with LTBI. If the prescribing physician does not have the most current information on treating LTBI, provide resources. Contact the WI TB Program if the physician needs to consult the WI TB Program medical consultant for decision-making in the treatment of persons with LTBI.

d. Fax the blank DPH 4000 (Rev. 7/00) to the physician if necessary and provide any needed instructions to the physician and/or office staff. Medication protocols approved by the ATS/CDC/WI TB Program are printed directly on page two of the DPH 4000 form including the dosage forms in which the medications are manufactured.

e. Review in advance what would be an expected ATS/CDC/TB Program approved medication regimen for this client, including calculating the dosage based on the person's weight and the dosage forms of tablets that are available.

f. Have the physician complete and fax the DPH 4000 to the WI TB Program or fax the prescription (s) to the TB Program while the health department completes the DPH 4000.

g. Ensure that the DPH 4000 for the client contains all the required information, including at a minimum all data elements marked with an asterisk (in the instructions) to ensure that the medication order is processed:

- Demographics, incl. apartment number, correct county, etc.
- **Weight** – required to do accurate medication calculations
- Physician demographics and DEA number
- **Skin test date and results** and reason for skin test, e.g. a contact to an active case – also name contact. [All information submitted to the State TB program is treated as confidential under Wis. Stat. 146.82(1)]
- **Chest x-ray date and results <u>within last six months</u>** – required to be sure active pulmonary TB disease has been ruled out
- Drug selection (or accompanying physician prescriptions) signed by the physician that meets one of the accepted ATS/CDC/TBP guidelines and can be filled with the dosages in which drugs are manufactured.

h. Compare the regimen prescribed by the physician to the ATS approved regimens and note any variations or complications.

i. Contact the physician after reviewing the prescription if you need more information about his/her rationale based upon your comparison of the prescription to the approved regimens. Phone the TB Program at 608-266-9692 with any questions.

j. Complete any missing data elements for the client on DPH 4000, including current weight, according to instructions on pages three and four accompanying the document. Do not delay sending it if some non-critical information is incomplete or pending.

k. Fax or mail page one of the completed form DPH 4000 with the signed physician's prescription on it to the WI TB. (Fax # - 608-266-0049) There is no need for you to return pages 2, 3 or 4 of the instructions back to the TB Program. Page one of the DPH 4000 form

and a copy of the physician's prescription faxed at the same time, properly identified, is acceptable. A fax of an original signature is equivalent to an original signature. The WI TB Program will evaluate the request and phone you or send a return fax pointing out any missing items. [*Fewer missing items expedite the process;* ***missing items result in delays in getting medications***.]

l. Receive by mail from the TB Program a packet of materials that alert you that the DPH 4000 has been processed and the medications are on their way to the local health department:

- A copy of the DPH 4000 with the TB Program's client identification (ID) number on it in the lower right hand corner,
- Forms DPH 4125 and DPH 4126 from the TB Program to use for refills and to submit when therapy is completed.
- Note: If this information does not arrive there may be a complication in your request.

m. Receive medications for the client within a week or two of when the TB Program receives the request.

- INH is supplied in 90-day increments, for RIF/PZA the two month supply is sent at one time.
- If the medications do not arrive promptly, something may be wrong with the request. First check if the WI TB Program has sent you the packet of information with a number in the lower right hand corner of the DPH 4000 that tells you it has been processed.

n. Supply the local pharmacy with the original prescription so they can dispense medication for the client **if** the medication is to be obtained locally. Provide them with the **Antituberculosis Therapy Authorization** with the **Client ID Number** and the **billing instructions** sent to you from the WI TB Program. Instruct the pharmacy in the correct direct billing procedures and answer their questions.

No tuberculosis client served by the WI TB Program, active disease or infection, is to incur any cost for antituberculous medications. The billing instructions clearly explain that insurance, including Medicaid is to be billed first, but ***clients do not pay*** *anything out of pocket, including deductibles or co-pays when the WI TB Program pays for medications.*

[*Continue to use the local pharmacy for medications for a client that has been started out with a local pharmacy supplier to avoid interruption in treatment or a delay for the client who has already begun treatment. It is important to avoid giving the impression that treatment for LTBI is not important. Clients who have never been started with the local pharmacy supply system can be started with drugs coming from the TB Program contract pharmacy through the public health department to ensure adherence to the regimen*.]

o. Go to the pharmacy if a local pharmacy is used and pick up the medications that the pharmacy has dispensed for the client, acting as his/her agent and deliver them to the client. Facilitate communication by phone between client and pharmacist if there are questions or issues the pharmacist or client would like to discuss.

p. Access the medications for the client from the secure health department cabinet or room following the portion of the procedure on medication safety and storage when the

medications have been dispensed through the WI TB Program contract pharmacy acting as an agent of the client.

3. **Establishing care and monitoring** for the client with LTBI.

a. Make a home visit to assess the client, obtain baseline history, evaluate for risk factors, assess for baseline signs & symptoms and clinical condition and to deliver the medication. (Refer to *Tuberculosis Nursing: A Comprehensive Guide to Patient Care*, p. 47-48.)

b. Educate the client and family regarding tuberculosis, importance of adherence and completion of therapy and assess for and implement methods and incentives, with client input, that will ensure adherence to therapy. [R*eference – ALA/W (American Lung Association of Wisconsin)*]

Part of the picture of world-wide TB elimination is ensuring that persons with infection receive complete treatment. The role of each public health department is critical if we are to take advantage of this "…wonderful opportunity to eventually eliminate this dreaded disease." [Phyllis J. Dubé Secretary, Department of Health and Family Services, March 13, 2001.]

c. Implement health department policies, procedures and practices for case management for latent TB infection that promote medication adherence and implement directly observed therapy (DOT) when indicated. National and CDC resources can be used for reference during policy and procedure updating. See reference lists.

- Assess clients with LTBI pre-treatment and re-assess through out treatment for DOT. Prioritize, if necessary, based on defined criteria. DOT is the standard of care in the health department for treatment of tuberculosis disease clients and suspects until active disease is ruled out. (Refer to *Tuberculosis Nursing: A Comprehensive Guide to Patient Care*, p. 77-83.)

- Recognize DOT as the only true assurance of completion of therapy for those who have tuberculosis infection (LTBI) when prioritizing resources. Treatment of persons with infection may require DOT, especially those who have high-risk medical conditions such as HIV+ status, those who are infected with multidrug-resistant tuberculosis, those who are suspected of non adherence and when DOT is needed to prevent outbreaks.

d. Assess all clients **face-to-face** pre-treatment and visit **at least monthly** [and at two, four and eight weeks for persons on RIF/PZA for two months] throughout therapy to provide education, and to assess for adverse reactions, signs and symptoms, risk factors, medication efficacy, side effects, adverse reactions, adherence to regimen, psychosocial and cultural issues related to the client and family and to deliver the medications. Implement appropriate measures to reverse any negative findings. (Refer to *Tuberculosis Nursing: A Comprehensive Guide to Patient Care*, p. 47-56.)

e. Reassess and re-educate as needed, according to the client's risk factors, **clinical condition**, and adherence issues but at least monthly unless recommended more often in the ATS/CDC guidelines for the LTBI treatment regimen. [e.g., Twice weekly RIF/PZA for two months is

to be monitored *at a minimum* during weeks two, four and eight due to increased risk of hepatic symptoms. Stay up-to-date with any further recommendations, as more information becomes available about alternate regimens. (MMWR, Volume 49, June 9th, 2000, pages 38 - 39 and MMWR, Volume 50, April 20, 2001 pages 289-291)]

f. Ensure that clients **with risk factors for hepatic disease have baseline and regular liver function testing**. If a physician is going to use liver function testing in decision-making about therapy for the person without risk factors for hepatic conditions, ensure that baseline liver function tests are drawn. Some physicians prefer initial liver function tests on all clients as a precaution so that if symptoms develop a baseline is available.

g. Assess and monitor signs & symptoms and clinical condition and **keep the physician informed** about possible adverse reactions to medications, especially signs of hepatic toxicity. Communicate nursing assessments of the individual to the physician to ensure that the physician has the critical clinical information to accompany any liver function laboratory findings. **Parameters for concern about transaminase levels (ALT) are different based on presence or absence of symptoms.**

h. Place medications on hold and facilitate a prompt evaluation if a person has transaminase levels **>three** times the upper limit ***with*** symptoms of hepatotoxicity and if the transaminase levels are **> five** times the upper limit for the person ***without*** symptoms of hepatoxicity.

i. Ensure that treatment is not interrupted unless necessary, but that signs and symptoms of hepatotoxicity are promptly evaluated as toxicity can progress rapidly and for some persons may become irreversible.

j. Call the TB Program for consultation promptly if therapy is interrupted.

k. Arrange for medication refills throughout therapy through the local pharmacy for clients with active disease or those clients who begin medications with the local supply method. Present any new prescriptions as needed directly to the approved pharmacy and notify the WI TB Program.

l. Order medication refills for most LTBI clients from the WI TB Program by submitting the **completed Refill Request form (DOH 4126)** to the TB Program **at least one month in advance**. Medication will be obtained as a 90-day supply that can be kept in the health department according to storage policy and procedure. Allow extra time for refills during holiday periods for pharmacy "back-up" by ordering well in advance.

m. Discuss any drug additions/deletions/changes (e.g. changing from isoniazid to rifampin or from daily to twice-weekly) or any deviation from ATS/CDC recommended regimens with the TB Program ***prior to submitting the refill request***.

n. Follow local health department policies, procedures and practices regarding medication delivery and storage for all tuberculosis medications in the health department, for both active disease and LTBI. See Section B. of procedure/guideline specific to medications.

o. Inform the WI TB Program of ***any*** changes in the client's medication regimen. This can be accomplished by phone, fax or mail and is needed to ensure medication reimbursement. Some examples of changes that require "new" prescriptions may include a change from daily therapy to twice weekly therapy.

p. Inform the WI TB Program of any changes in the client's Medicaid status during therapy by phone or fax or directly on the refill order, DOH 4126. (e.g., after the initial prescription for which the WI TB Program is billed, client becomes eligible for Medicaid. Once they are Medicaid eligible, Medicaid is their primary payer.)

q. Collaborate with the staff, infection control practitioners and/or discharge planners for the person discovered to be infected who is hospitalized or in an institution. Ensure that the necessary medications for appropriate treatment of LTBI are being supplied and administered and that proper monitoring is in place. Provide education as needed.

r. Ensure that there will be no interruption in therapy after institutional discharge. Coordinate with the institution's discharge planning services to help with this. Coordinate with the prescribing physician and the pharmacy if there are any changes in physician or pharmacy so that therapy for LTBI is not interrupted.

s. Ensure adherence to an approved medication regimen throughout completion of care using health department policies, procedures and practices related to DOT and Case Management.

4. **Closing out the case of the person with LTBI** with the TB Program:

a. **Submit a DPH 4125 form with all data elements completed for <u>each client</u> who receives treatment through the health department for latent tuberculosis infection (LTBI) to close the record at the WI TB Program.** This includes both the persons who get the medication supplied from the TB Program central pharmacy and the ones whose medications come from a local pharmacy but are funded by the WI TB Program. **This information is critical for complete data analysis and evaluation of completion of therapy rates in Wisconsin.**

> *Take credit for your hard work serving clients with LTBI;* ***report your data****!*

b. Send a **DPH 4125 form** (Follow Up on Therapy) to notify the WI TB Program when the LTBI medication is no longer to be delivered to the health department for any reason (e.g., client moved, expired, completed therapy, etc.)

c. **Notify the TB Program by phone** (608-266-9692) when a suspect of active disease is confirmed as infected only and **active disease is ruled out**.

d. **Notify the TB Program by phone** (608-266-9692) for a complete closure consultation for **each active disease** case when the person completes therapy or transfers. See procedure for persons who move out of the jurisdiction of your health department in Section A. on Persons with active disease.

A. WI Tuberculosis Program – Communication, Services & Resources, con't.

- **Persons with special reporting requirements and needs (e.g. immigrants, refugees, K 1 fiancés, etc.)**

1. Ensure that policies, procedures and practices are in place at the health department that provide for the collection of critical information during the intake process.

2. Recognize the importance of **prompt follow-up** for these individuals because

   a. The overseas chest x-ray, sputum evaluation and decision about their possibility of being infectious may have been done quite a while ago and **may no longer reflect their current tuberculosis status.**

   b. There is great potential for persons to become infectious during their travels even though they may have been considered not infectious when they were evaluated in their home country. The process of coming to the United States may have been long, stressful, and unhealthy and medication therapy may not have been taken even if it was prescribed/indicated.

   c. No skin testing is done during the process of coming to the United States.

3. Receive information about an immigrant or refugee with tuberculosis disease or infection in one of the following common manners:

   a. A letter from the WI TB Program arrives with enclosed information from the CDC Division of Quarantine or another state's health department. This letter describes the role of the health department with emphasis on:
      - **Securing the medical evaluation for the client to rule out active disease and/or begin treatment for disease or infection, and**
      - **Returning the Report on Alien With Tuberculosis ,CDC 75.17 form, to the WI TB Program to complete the reporting requirements.**

   b. A client may walk into the health department with a need for follow up related to TB infection or disease

4. Recognize the following classification of immigrants and refugees related to their TB evaluations prior to coming to the U.S. to guide your decision-making and use of health department resources:

   The primary role of the health department with *each* of these categories of persons is to apply and read a TB skin test and facilitate a *prompt* medical evaluation:

Persons born outside the United States now account for 52 % of reported cases of active TB disease in Wisconsin.

TB Skin testing is *not* performed in other countries or at U.S. ports of entry.			
Classification	**Overseas CXR**	**Overseas sputum AFB Smears**	**Restrictions & Comments**
B1	Abnormal, suggestive of active tuberculosis. Person should have their film with them.	Negative smear For AFB (was not considered infectious when overseas)	Client has been instructed to report to the local health department in the U.S. for further medical evaluation within 30 days of arrival. May be on medications but may need more ASAP.
B2	Abnormal, suggestive of inactive tuberculosis. Person should have their film with them.	Sputums have *not* been done	Client has been instructed to report to the local health department in the U.S. for further medical evaluation within 30 days of arrival.
B3	CXR = Tuberculosis, old or healed. May have their film with them.	Sputums have *not* been done	Client is a candidate for targeted TB skin testing/medical evaluation as treatment for LTBI may prevent progression to active disease.
A Waiver	Abnormal, suggestive of active TB. Person should have their film with them.	Positive smear for AFB – considered infectious	Do not enter U.S. until treatment has been underway overseas & sputum smears are negative, but they may be in urgent need of more medications.
Rarely does a person with an A waiver enter the U.S.; they are excluded from this procedure. Contact the WI TB Program immediately for assistance/reporting if you have a person with an A classification.			
Persons with VISAs for school, work, business, migrant laborers and undocumented persons do not have CXRs done in their home country and there is no notification process or paperwork from the Immigration/Nationalization Service (INS) when they enter the U.S.			

5. Locate the client when you receive a Report on Alien with Tuberculosis form (B1 or B2 "yellow form") and the packet of information from the TB Program. It is possible the person has become infectious between the time they left their home country and the time they arrive in Wisconsin. **They require urgent public health action.**

6. Provide interactions that are culturally sensitive and take psychosocial issues into consideration. Secure interpreters when indicated.

7. Provide TB skin testing and facilitate a medical evaluation for the client as soon as possible.

8. Ensure proper documentation and reporting of public health actions regarding application and reading of skin test and facilitating the medical evaluation follow-up by proper completion of the Report on Alien with Tuberculosis, including

    a. Skin test result in millimeters of induration and significance for risk factors

    b. **Physician's signature** and date and

    c. **Returning it to the WI TB Program** (Retain a copy for your client's record.)

    d. Preventing the physician's office from sending it to CDC. Do not send it to CDC from the health department.

    The WI TB Program is responsible for ensuring that immigrants and refugees receive proper follow up by the local health department, that all the information is entered into the TB Program's data base and that prompt reporting to CDC is completed.

9. Facilitate application for medical assistance promptly for those believed to be eligible. See grid at the end of this procedure "Medical Assistance (MA) Benefits for Persons with Tuberculosis (TB)" for further information. Consult and collaborate with your county/tribal experts who handle MA applications and eligibility.

    a. Refugees are eligible for medical assistance for at least the first 90 days, however, enrollment may not yet be done.

    b. Refugees may qualify for continued Medical Assistance benefits after 90 days if they meet financial eligibility requirements.

    c. Immigrants are not eligible for Medical Assistance for the first five years unless they have an emergency medical condition. Immigrants without insurance and no funds are able to look to their U.S. sponsor for help.

    d. Migrant workers who are U.S. citizens have the same rights to services and Medical Assistance as all U.S. citizens.

10. Use any available community agencies or resources who provide support for persons coming to the United States when there are difficult financial issues.

11. Follow health department policies, procedures and practices for initiating services and ordering medications for persons with active disease or LTBI as with all persons.

B. Receipt, Storage and Control of TB Medications in the Health Department.

1. Receipt of medications

    a. Pick up the medications dispensed from the local pharmacy for the client who is a suspect, the client with active disease or persons with high-risk medical conditions who are on treatment for infection or window prophylaxis, acting as an agent of the client(s).

    b. Receive the medications dispensed for a client with infection (LTBI) via the WI TB Program delivery system, acting as an agent of the client for any person not receiving medications through the local pharmacy. A person who is not a young child (four or under) or does not have a medical risk factor, such as being HIV+ will get their medications sent to the local health department from the WI TB Program central contract pharmacy.

    c. Determine that the medication dispensed by the pharmacy is the correct prescribed medication [right medication, right dose, (right strength and correct number of tablets), right frequency for the right patient] and complete entries on these **two** local health department forms to document safety and control of TB medications and health department actions:

        - Drug Receipt/Delivery – retained in the client's record
        - Tuberculosis Drug Inventory Log – retained in the drug control area

2. Storing and safeguarding TB medications in the Health Department

    a. Ensure safe storage of medications in the health department and prevent contamination, adulteration or exceeded expiration dates with precautions for proper control, storage and destruction of tuberculosis medications.

    b. Store drugs in the original containers in which they are dispensed. Do not transfer medications from one container to another.

    c. Store drugs not requiring refrigeration in a controlled location away from public access in a [locked cabinet or locked medication room] [*choose one for final procedure document per local health department decision*] that is kept at no more than 85 degrees F. (29 degrees C.).

    d. Store drugs that require refrigeration, such as Streptomycin or PAS, in a closed container in a refrigerator maintained at 35° to 46° Fahrenheit (2° to 8° Centigrade) that is plugged in to a live "unswitched" outlet and maintain quality control of refrigerated drug storage by:

        1. Avoiding use of refrigerator door for storage,
        2. Checking and documenting refrigerator temperatures at least daily according to health department policies, procedures and practices that are part of the monitoring process for biological/immunization products (35° - 46 ° F., 2° - 8° C.)
        3. Correcting immediately, at the source of the problem, if there are any deviations outside temperature monitoring parameters,

4. Taking corrective action in the event of any interruption in power, such as maintenance staff notifying the health officer or designee, as specified in health department policies, procedures or practices related to interruption of power.

e. Maintain control of access to medications and drug safety by:

1. Approving access to medications only upon authorization by the health officer or designee
2. Restricting access to medications only to registered nurses or personnel authorized as above (e.1.) with specific education and delegation by a registered nurse. (e.g., support staff who handle incoming mail are instructed and supervised in the process of placing unopened boxes that arrive from pharmacies in a secure area until a nurse accesses the medications; an authorized (e.1.) DOT worker who is educated and supervised by the registered nurse administers medication by DOT, etc.)
3. Assuring that the medication cabinet/room is locked and key(s) secured
4. Receiving, documenting and securing new medications that arrive
5. Documenting with signed and dated entries according to health department practices on the following two forms for medication control and tracking:

   a. Client Drug Receipt/Delivery Form should be kept in the client's chart to document the receipt or pick-up of all medication to treat TB infection or disease document control and tracking with entries such as:
      - Medications and doses, original scripts and refills
      - Dates requested, received and delivered
      - Number of tablets delivered
      - Refill tracking system for advance ordering

   a. Document if client receiving DOT [DOT documentation details are recorded separately.]
   b. Record of doses taken and doses missed for analysis and documentation of completion of therapy for the person who self-administers, including any interruptions.
   c. Dates, initials, signatures per agency practice

6. Tuberculosis Drug Inventory in the medication storage area is a form that may be used to record receipt, storage and disposition of all TB medications held at the local health department. One line should be used for each shipment/pick-up of each drug for each client. Document items such as:
   - Date received
   - Client's name
   - Name of drug(s)
   - Number of bottles
   - Disposition action (delivered, destroyed)
   - Number of bottles remaining (another cue for advance re-ordering)
   - Dates, initials, signatures per agency practice

7. Destroying medications when necessary using the following criteria: (Medications are not returnable.)

   - Discard in the septic system or municipal sewage system by flushing
   - Destroy labels with patient's names prior to disposing of bottles
   - Dispose of *empty*, *unlabeled* bottles in office receptacles

f. Ensure a medication reorder system that prevents accumulation of duplicate medications and avoids appeals for "rush" orders. Plan ahead and use advance reordering with both the WI TB Program and any local pharmacies that are utilized.

g. Stop the flow of unneeded medications by communicating promptly with the WI TB Program following criteria below: See each procedure section for care of persons with active or suspect disease and persons with LTBI for *complete* information.

   1. Send a **DPH 4125 form** (Follow Up on Therapy) to notify the WI TB Program that the medication is no longer to be delivered to the health department (e.g., client moved, expired, completed therapy, etc.)

   2. A **DPH 4125 form is <u>required</u> for <u>each client</u>** who receives treatment for latent tuberculosis infection **(LTBI)** through the local health department. This includes both the persons who get the medication supplied from the TB Program central pharmacy and the ones whose medications come from a local pharmacy but are funded by the WI TB Program. **This information is critical for complete data analysis and evaluation of completion of therapy rates in Wisconsin for the clients you are serving with LTBI.**

   3. **Notify the TB Program by phone** (608-266-9692) when a suspect of active disease is confirmed as infected only and **active disease is ruled out**.

   4. **Notify the TB Program by phone** (608-266-9692) for a complete closure consultation for **each active disease** case when the person completes therapy or transfers.

Local Health Department Tuberculosis Drug Inventory

Date Rec'd	Client's Name	Drug Name	# of Bottles Rec'd	Disposition			Witness Signature for Destroying Medication/ Reason for Destroying
				Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	
				Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	
				Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	
				Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	
				Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	
				Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	Bottle # ___________ Date: _____________ ☐ Delivered ☐ Destroyed # of bottles remaining: _________ Staff Initials: _______	

Initials: _________ Signature/Title: ____ Initials: _________ Signature/Title: ____

Initials: _________ Signature/Title: ____ Initials: _________ Signature/Title: ____

Local Health Department Tuberculosis Drug Inventory

Instructions

This form may be used to record receipt, storage, and disposition of all TB medications held at the local health department. One line should be used for each shipment/pick-up of each drug for each client.

Date Rec'd Record date medication was received.

Drug Client's Name Record client's name.

Name Record name of drug.

# of Bottles Rec'd Record the number of bottles received during that shipment/pick-up for that drug.

Disposition
Use one box per bottle of medication received in that shipment/pick-up.

Bottle # Count the number of bottles received in the shipment/pick-up. Assign each bottle a number.

Date, Delivered, Destroyed Indicate the date the medication was removed from health department storage and the reason for removal (delivered, destroyed).

# of bottles remaining Indicate the number of bottles still held by the health department.

Staff initials Initial removal of medication.

Witness signature for destroying medication/reason for destruction Sign as needed to confirm medication was destroyed and the reason for destruction. (Client moved, lost, physician discontinued, etc.)

Initials, Signature/Title Include initials and corresponding signature of each person recording information on the form.

EXAMPLE:

Date Rec'd	Client's Name	Drug Name	# of Bottles Rec'd	Disposition			Witness Signature for Destroying Medication/ Reason for Destroying
1/20/01	Doe, Jane	INH	3	Bottle # 1 Date: 1/21/01 ☒ Delivered ☐ Destroyed # of bottles remaining: 2 Staff Initials: TVO	Bottle # 2 Date: 2/15/01 ☒ Delivered ☐ Destroyed # of bottles remaining: 1 Staff Initials: TVO	Bottle # 3 Date: 3/15/01 ☒ Delivered ☐ Destroyed # of bottles remaining: 0 Staff Initials: TVO	
1/20/01	Doe, James	RIF	2	Bottle # 1 Date: 1/21/01 ☒ Delivered ☐ Destroyed # of bottles remaining: 1 Staff Initials: TVO	Bottle # 2 Date: 2/15/01 ☐ Delivered ☒ Destroyed # of bottles remaining: 0 Staff Initials: TVO	Bottle # _____ Date: __ ☐ Delivered ☐ Destroyed # of bottles remaining: _____ Staff Initials: ___	Discontinued, prescription changed
1/20/01	Doe, James	PZA	2	Bottle # 1 Date: 1/21/01 ☒ Delivered ☐ Destroyed # of bottles remaining: 1 Staff Initials: TVO	Bottle # 2 Date: 2/15/01 ☐ Delivered ☒ Destroyed # of bottles remaining: 0 Staff Initials: TVO	Bottle # _____ Date: __ ☐ Delivered ☐ Destroyed # of bottles remaining: _ Staff Initials: ___	Discontinued, prescription changed

CLIENT DRUG RECEIPT/DELIVERY FORM

Name: _____ **Birth Date:** _____ **Telephone:** _____

Address: _____ **County of Residence:** _____

Health Department: _____ **Prescribing Physician:** _____ **Telephone:** _____

DOT ☐ **No** ☐ **Yes** **If Yes, DOT done by:** ☐ **Health Department staff*** ☐ **Other responsible person** ☐ **Other provider**

*Refer to DOT documentation for delivery information

Drug	Dose/Frequency	Bottle # _____ ☐ Original ☐ Refill								Bottle # _____ ☐ Original ☐ Refill							
		Date Requested	**Date Received**	**# of Tablets Received**	**Date Delivered to ____**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed (not future doses)**	**Date Requested**	**Date Received**	**# of Tablets Received**	**Date Delivered to ____**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed (not future doses)**
INH																	
RIF																	
PZA																	
Ethambutol																	
Other																	
Other																	

DOT ☐ **No** ☐ **Yes** **If Yes, DOT done by:** ☐ **Health Department staff*** ☐ **Other responsible person** ☐ **Other provider**

*Refer to DOT documentation for delivery information

Drug	Dose/Frequency	Bottle # _____ ☐ Original ☐ Refill								Bottle # _____ ☐ Original ☐ Refill							
		Date Requested	**Date Received**	**# of Tablets Received**	**Date Delivered to ____**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed (not future doses)**	**Date Requested**	**Date Received**	**# of Tablets Received**	**Date Delivered to ____**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed (not future doses)**
INH																	
RIF																	
PZA																	
Ethambutol																	
Other																	
Other																	

Date therapy was started: _____ Date therapy was completed: _____ No. of days therapy was interrupted: _____

All of the recommended therapy was completed: ☐ Yes ☐ No If no, explain: _____

Initials: _____ Signature/title: _____ Initials: _____ Signature/title: _____

Initials: _____ Signature/title: _____ Initials: _____ Signature/title: _____

Client Drug Receipt/Delivery Form

Instructions

This form may be used to document the receipt/pick-up and delivery of all medication to treat TB infection or disease. This document may also track client adherence to therapy and should be kept in the client's chart.

Top of the form
Note the client's name, birth date, telephone, address, and county of residence. Include the name of the health department, prescribing physician, and physician's telephone number.

Medication
Indicate whether the client is receiving directly observed therapy (DOT). If yes, indicate whether DOT is provided by health department staff, delegated to another responsible person (e.g. clergy, group home staff, etc.) or performed by another provider (home health agency, jail nurse, etc.). For clients receiving DOT from the health department, delivery information is recorded on the DOT documentation instead of this form. For clients receiving DOT from a delegated responsible person or agency outside the health department, delivery to the DOT **provider** is documented on this form. The DOT provider is responsible for documenting DOT on appropriate paperwork.

Drug, Dose/Frequency
Indicate the dose and frequency of administration for each drug prescribed.

Bottle #, Original, Refill
Each bottle has it's own section of the table to record receipt, delivery, and adherence information. Indicate which bottle of medication the section refers to (1,2, 3, etc.)

Indicate whether this bottle is part of an original order or a refill order. For clients whose medication is supplied monthly by the local pharmacy, the Bottle #1 will be "original" and all future bottles will be "refill." For clients whose medication is supplied from the WI TB Program pharmacy, multiple bottles may be part of the "original" order as medication is typically supplied in 2-3 month amounts.

Date Requested
Record the date the prescription was submitted to the Wisconsin TB Program or the local pharmacy.

Date Received
Record the date the medication was received from the Wisconsin TB Program pharmacy or picked-up from the local pharmacy.

# of tablets received
Count and record the total number of tablets received in that bottle. This should usually be a 30 days' supply.

Date Delivered to
Record the date the medication was delivered and to whom it was delivered (e.g. client, group home, jail nurse, etc.)

# of Tablets delivered
Record the actual number of tablets delivered.

Delivered by (initials)

# of doses taken, # of doses missed
When delivering subsequent bottles of medication, assess medication adherence by first calculating the number of doses of medication and number of pills that **should have been taken** from the prior delivery. Based on a pill count of the remaining medication and the number of pills prescribed, calculate the number of doses taken and the number of doses missed. Record the actual number of doses taken. Record the actual number of doses missed. **Remaining pills to be taken for future doses** (medication delivery occurs before the client runs out of medication) **should not be counted as missed doses.**

Date therapy was started
Record date client began taking the medication. This date will be the same on the first and any additional pages of documentation.

Date therapy was completed, No. of days therapy was interrupted
Record the date the client completed the course of therapy. Indicate any therapy interruptions during the entire treatment period.

All of the recommended therapy was completed, If no explain
After the client has stopped taking the medication, indicate whether the recommended therapy was completed. If not, indicate the reason (e.g. moved, lost, adverse reactions, other medical reason, declined).

Initials, Signature/title
Each person initialing the form should include their signature and title in this section.

Example 1:
300 mg INH, taken daily as one 300 mg tablet, self-administered, received as a 3 month supply from the WI TB Program pharmacy

DOT ☒ No ☐ Yes If Yes, DOT done by: ☐ Health Department staff* ☐ Other responsible person ☐ Other provider
*Refer to DOT documentation for delivery information

Drug	Dose/Frequency	Bottle # __1_____ ☒ Original ☐ Refill								Bottle # __2_____ ☒ Original ☐ Refill							
		Date Requested	**Date Received**	**# of Tablets Received**	**Date Delivered to _Client**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed**	**Date Requested**	**Date Received**	**# of Tablets Received**	**Date Delivered to Client**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed**
INH	300 mg daily	1/10/01	1/20/01	30	1/21/01	30	TVO	25	0	1/10/01	1/20/01	30	2/15/01	30	TVO		

30 pills were delivered in the first bottle. When the second bottle was delivered 25 days later, there were 5 pills remaining in the first bottle. The client had taken 25 doses and had not missed any doses to date.

Example 2:
First month: 600 mg RIF taken daily as two 300 mg tablets, 1500 mg PZA taken daily as three 500 mg tablets, delivered to jail health staff for directly observed therapy, picked up monthly at the local pharmacy. Second month: due to adverse reaction, medication switched to 300 mg daily INH.

DOT ☐ No ☒ Yes If Yes, DOT done by: ☐ Health Department staff* ☐ Other responsible person ☒ Other provider
*Refer to DOT documentation for delivery information

Drug	Dose/Frequency	Bottle # __1_____ ☒ Original ☐ Refill								Bottle # __1_____ ☒ Original ☐ Refill							
		Date Requested	**Date Received**	**# of Tablets Received**	**Date Delivered to _jail nurse**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed**	**Date Requested**	**Date Received**	**# of Tablets Received**	**Date Delivered to jail nurse**	**# of Tablets delivered**	**Delivered by (Initials)**	**# of doses taken**	**# of doses missed**
INH	300 mg daily									1/27/01	1/28/01	30	1/28/01	30			
RIF	600 mg daily	1/10/01	1/11/01	60	1/11/01	60	TVO	15	0								
PZA	1500 mg daily (taken together)	1/10/01	1/11/01	90	1/11/01	90	TVO	15	0								

30 doses were delivered with the first bottle, 60 capsules of RIF and 90 tablets of PZA. The physician ordered the medication to be stopped after 15 doses had been taken, due to side effects. No doses were missed up to that point. The physician then ordered INH.

C. Accessing Wisconsin State Laboratory of Hygiene Services

➢ AFB (Acid Fast Bacilli) Testing

All local health departments in Wisconsin may submit specimens to the Wisconsin State Laboratory of Hygiene (WSLH) free of charge. Specimens may be transported to the WSLH without cost using the contracted delivery service.

1. Collection kits

   a) Order collection kits by calling the WSLH number for clinical supplies: (800) 862-1088, or (608) 265-2966. Operators are available to take telephone orders Monday through Friday from 7:45 a.m. to 3:30 p.m. Specify Mycobacteria Culture kit #8. Store kits at the health department indefinitely.

   b) Obtain specimen collection materials from another source (local hospital, clinic, or physician's office) if no kits are available at the health department and specimen collection must occur prior to receipt of kits from WSLH. Assemble the following materials: sterile container with a tight-fitting screw-top cap, a container label, biohazard labels, 2 plastic zipper bags, paper towel, mailing box, packing material, and sealing tape.

2. Order Immunology-Microbiology requisition forms pre-printed with the health department fee exempt account number, as needed, by calling 1-800-862-1088.

3. Obtain appropriate specimens according to health department specimen collection policies, procedures, and practices. Collect multiple specimens on different days. [*Resource: Francis J. Curry National Tuberculosis Center, Institutional Consultation Services. Conducting Sputum Induction Safely. 1999. Available online at http://www.nationaltbcenter.edu/tbcontrol/induction.html*]

4. Submit each specimen to the laboratory as soon as possible. When transport allows, submit the specimen on the day it is collected. Refrigerate if there is a delay in submitting.

5. Tighten the cap on specimen container to prevent leakage in transit. Write the patient's name and date collected on the container label and firmly affix the label to the container.

6. Complete the Immunology-Microbiology test request form using the local health department fee exempt account number. One form is required per specimen. If patient has started TB medication, indicate which medications and treatment start date in the space labeled "Additional." Check test #650: Mycobacteriology (TB) Smear and Culture (AFB).

7. Wrap the specimen container in absorbent material (such as a paper towel). Place the wrapped specimen container in zipper portion of a biohazard bag (or other plastic zipper bag labeled "biohazard") and zip close. Place the request form in the rear pouch of the biohazard bag or in a separate zipper bag. Place the closed bag(s) in a styrofoam or other mailing container and seal with tape. Label the mailing container as "clinical specimen" and attach a biohazard label.

8. Arrange for delivery of specimens to the laboratory using Dunham Express or Express Mail. Use Dunham Express rather than Express Mail whenever possible, especially in Milwaukee. Refer to the twenty-four hour delivery instructions that follow.

TWENTY-FOUR HOUR DELIVERY
MYCOBACTERIOLOGY SPECIMENS
WISCONSIN STATE LABORATORY OF HYGIENE

DUNHAM EXPRESS

Note: *Please phone Dunham now to find out the time of day by which you must notify Dunham for same day pick-up (varies with location). Note time of day below.*

Notification Time _____

Dial 1-800-236-7127 to reach the Dunham processor.

Give the processor the following information:

- **The WSLH-Mycobacteriology account number: 7271**
- Your name
- Your pick-up address
- Other location information (e.g. Room number)
- Destination:
  Mycobacteriology Laboratory
  State Laboratory of Hygiene, Room 121
  465 Henry Mall
  Madison, WI 53706
- Shipment description: Clinical specimen

Specimens will be picked up during regular working hours, confirm the time of pick-up with the processor.

Specimen arrives at WSLH **by 10:00 am** of the day following the day of pick-up.

EXPRESS MAIL

Options: Give to local US postal carrier
Call post office for pick-up
Deliver to the local post office

NOTE: We strongly recommend using Dunham Express rather than Express Mail whenever possible, especially for Milwaukee customers.

- Attach the *Post Office to Addressee* form (available from the local carrier or the local post office) to the package

- Indicate the WSLH **Mycobacteriology Account Number 537-351** for Method of Payment on label form

- Address to:
  Mycobacteriology Laboratory
  State Laboratory of Hygiene, Room 121
  465 Henry Mall
  Madison, WI 53706

Specimen arrives at WSLH **by noon to 3:00 p.m.** of the day following the day of pick-up.

Smear results are available Monday-Friday at 2:30 p.m. Smear results for specimens received by 10:00 a.m. will be available the same day. Smear positives on new patients will be phoned to the submitting source and the WI TB Program. Hard copies of all results (positive or negative) will be mailed to the submitting source. *Mycobacterium tuberculosis* Direct (MTD) results will be available by 4:30 p.m. All MTD results will be phoned to the submitting source and the WI TB Program.

Packaging is the same for either Carrier. Use WSLH sputum kit #8 for diagnostic clinical specimens. Infectious agents (isolates) must follow the specific containment packaging and labeling requirement of the US Post Office for etiologic agents. Phone (608) 262-1618 for specific information.

Smear Results

1. Receive smear results from the laboratory or the WI TB Program. Request results from the WSLH microbiology department 608/262-1618 if none have been received within 24 hours. Interpret the results considering the following information:

   a. After submission to the laboratory, specimens are processed to create a homogeneous mixture and inhibit other bacteria. Once processed, specimens are set up for both acid fast bacilli (AFB) smear and culture.

   b. Smear results are available Monday-Friday at 2:30 p.m. Smear results for specimens received by 10:00 a.m. will be available the same day. Smear positives on new patients will be phoned to the submitting source (the person/agency listed on the requisition form) and the WI TB Program. Hard copies of all results (positive or negative) will be mailed to the submitting source.

   c. Smears are used for presumptive diagnosis of mycobacterial disease and rapid identification of the most infectious cases of tuberculosis. It is much less sensitive than culture for detecting mycobacteria.

   d. The fluorochrome method is the preferred method of AFB smear and is used by the WSLH. Other laboratories may use other techniques, such as Ziehl-Neelsen or Kinyoun.

2. **Presume a patient with a positive smear to have infectious tuberculosis until proven otherwise.** Refer to health department policies, procedures and practices regarding tuberculosis infection control, isolation and confinement. Remember that a positive smear is not conclusive for *M.tuberculosis*; it simply means that there are ***mycobacteria*** in the specimen. Further testing is needed to identify whether they are ***tuberculosis mycobacteria***, or ***non-tuberculosis mycobacteria***.

3. Note the number of acid fast bacilli (AFB) seen to indicate level of infectiousness and use this information when conducting the contact investigation.

*Sputum smear, translation of infectiousness**	
If lab reports:	*Patient is:*
None, no AFB seen, negative	*Potentially infectious ++*
Rare, 1+, 1-9 afb/100 oil immersion fields	*Possibly infectious*
Few, 2+, 1-9 afb/10 oil immersion fields	*Probably infectious*
Moderate, 3+, 1-9 AFB/oil immersion fields	*Probably infectious*
Numerous, many, 4+, >9 AFB/oil immersion fields	*Probably very infectious*

++ 100,000 organisms per milliliter of sputum are necessary for a positive smear result. A person with pulmonary tuberculosis and negative smears could potentially be infectious, but is less likely to be infectious than persons with positive smears.

[*Adapted by the WI TB Program from information in *Tuberculosis Nursing: A Guide to Patient Care*, p. 87]

Nucleic Acid Amplification (NAA) Testing

1. Consider whether NAA testing will be performed on the specimen based on the following information:

   a. General test information:

   - The test detects genetic material from *M. tuberculosis* and is therefore both confirmatory and more sensitive than smear results alone.
   - Test results are available in 24 hours.
   - The FDA approved use of this test is limited to respiratory specimens only (sputum, bronchial wash, bronchial aspirate).
   - The WSLH uses Gen-probe's NAA test called *Mycobacterium tuberculosis* Direct (**MTD**) which tests for the RNA of the TB organism. Another FDA approved test, made by Roche called Amplicor, is a polymerase chain reaction (PCR)-based test for DNA of the TB organism.

   b. The WSLH will automatically perform the **MTD** test on AFB smear *positive* respiratory specimens if:

   - The specimen was received within 24 hours of collection and is free of visible blood
   - The patient has not been on medication more than 7 days

   c. The WSLH will perform the test **upon request** on smear negative respiratory specimens if:

   - The specimen was received within 24 hours of collection and is free of visible blood
   - The patient has not been on medication more than 7 days
   - The patient has signs and symptoms of TB and risk factors for exposure

   d. The WSLH will also perform the test **upon request** for respiratory specimens processed in other laboratories if

   - The specimen was processed by the other lab within 24 hours of collection and is free of visible blood
   - The specimen is received by the WSLH within 72 hours of processing
   - The patient has not been on medication more than 7 days

2. Request the MTD test, if warranted, on smear *negative* specimens by calling the WSLH microbiology department 608/262-1618.

3. Call the WI TB Program to discuss the appropriateness of requesting the MTD test on a specimen processed by another laboratory.

   a. If appropriate, facilitate submission of the **processed sediment** to the WSLH by discussion with the physician, infection control practitioner and/or laboratory.

b. Advise the submitting laboratory that the test will be performed free of charge. **Share the "Information Sheet for Nucleic Acid Amplification Testing *for Mycobacterium tuberculosis* complex" and the "Twenty-four hour delivery" information with the laboratory to expedite transport of the sediment.**

4. Receive MTD test results considering the following:

   a. MTD results are available from the WSLH by 4:30 PM.
   b. All MTD results are phoned **to the submitting source** and the WI TB Program.
   c. **Call** the WSLH microbiology department 608/262-1618 if results have not been received **within 24 hours.**

5. Interpret MTD test results considering the following:

   Two or more specimens may be required for testing. Multiple negative results may exclude **INFECTIOUS** tuberculosis. Refer to specific information below and on the "Information Sheet for Nucleic Acid Amplification Testing" and "Nucleic Acid Amplification (NAA) Testing Algorithm for *M. tuberculosis* complex".

   a. Smear Positive Specimens

   1. First specimen is **NAA-positive** **Patient can be presumed to have TB**.
   2. First specimen is NAA-negative
      a. Inhibitors are NOT detected

         Test 1 to 2 additional specimens collected on different days.
         Patient can be presumed to have non-tuberculous mycobacteria if a second specimen is smear-positive, NAA-negative, and no inhibitors are detected.

      b. Inhibitors are detected

         NAA test is of no diagnostic help. Presence of inhibitors in specimen is reported.
         One to two additional specimens collected on different days can be tested. If inhibitors are detected in follow-up specimen(s), NAA test is of no diagnostic help. Culture results are then necessary to determine presence or absence of *M. tuberculosis*.

   b. Smear Negative Specimens

   1. First specimen is NAA-positive

      Test 1 to 2 additional specimens collected on different days.
      Patient can be presumed to have TB if a subsequent specimen is NAA-positive.

   2. First specimen is NAA-negative
      a. Inhibitors are NOT detected

Test an additional specimen collected on a different day.
Patient can be presumed to be *non-infectious* if second specimen is also smear negative, NAA-negative, and does not contain inhibitors, but negative NAA result *does **not** exclude the possibility of active pulmonary TB.*

b. Inhibitors are detected

NAA test is of no diagnostic help. Presence of inhibitors in specimen is reported.
One to two additional specimens collected on different days can be tested. If inhibitors are detected in follow-up specimen(s), NAA test is of no diagnostic help. Culture results are then necessary to determine presence or absence of *M. tuberculosis.*

6. If repeat NAA testing fails to verify initial NAA test results, the clinician must rely on clinical judgement in decisions regarding anti-TB therapy, further diagnostic work-up, and patient isolation.

Information Sheet for Nucleic Acid Amplification Testing for *Mycobacterium tuberculosis* complex

The Wisconsin State Laboratory of Hygiene (WSLH) offers the Gen-Probe Amplified *Mycobacterium tuberculosis* Direct (MTD) Test, a target-amplified nucleic acid probe test for the in-vitro detection of *M. tuberculosis* complex rRNA. The MTD test (test code #683, CPT code 87556) is used as an adjunct test to culture.

The WSLH has been performing the MTD test since 1996 on initial acid-fast bacilli (AFB) smear positive specimens. The second generation of the MTD test has been in use since August, 1998. Between August, 1998, and August, 2000, 110 AFB smear-positive specimens tested by MTD at WSLH also had culture results. When testing these 110 specimens, the MTD test had a sensitivity of 80% (20/25) and specificity of 100% (85/85) compared to culture. Only one specimen per patient was tested. Testing for the presence of substances that inhibit amplification was not performed. Effective August, 2000, WSLH now routinely tests all specimens for the presence of inhibitors and also recommends testing a second specimen on smear positive patients when the first specimen is MTD negative. See the attached MTD testing algorithm. Following this new testing protocol, we expect that the test sensitivity on smear positive specimens will meet the 95.5% sensitivity published by Gen-Probe.

The MTD test now has FDA-approval for testing smear negative specimens. WSLH will perform the MTD test on smear negative specimens from patients when the index of suspicion for tuberculosis is high (signs and symptoms of TB and risk factors for exposure). At least two specimens collected on different days should be tested on smear negative patients regardless of the MTD results on the first specimen. See attached MTD testing algorithm.

Submission of Specimens

There is **NO CHARGE** for this test when performed on specimens meeting DPH criteria for testing. Funding for approved specimens is provided by the Division of Public Health (DPH) Tuberculosis Program and the WSLH. **Notify the WSLH TB Laboratory (608) 262-1618 or the DPH Tuberculosis Program (608) 261-9692 before submitting specimens for MTD.**

MTD testing is performed at WSLH Monday through Friday.
Primary specimens collected on Thursday or Friday must be received by Friday morning to be acceptable for MTD testing.
If submitting processed sediments for MTD testing, sediments that are processed on Thursday must be received by noon on Friday and sediments processed on Friday must be received by noon on Monday.

Acceptable specimens types for MTD testing include:
A. A primary sputum, tracheal aspirate, or bronchial washing
B. A sediment from an appropriately decontaminated sputum, tracheal aspirate, or bronchial washing

See attached MTD testing algorithm for specimen criteria

When testing more than one specimen per patient is warranted, specimens must be collected on different days.

PATIENT CRITERIA

AFB smear positive patient not previously (recently) diagnosed with TB or non-tuberculosis mycobacteria infection
AFB smear negative patient with signs and symptoms of TB and risk factors for exposure
Patient has received $\leq$ 7 days of anti-TB treatment or no such treatment within the last 12 months

If patient and specimen meet the criteria for MTD testing and you are ready to send the specimen, or if you would like more information please contact the WSLH Mycobacteriology Laboratory at (608) 262-1618. Remember to use the **Twenty-Four Hour Delivery, No Extra Charge** service funded by DPH/WSLH.

Nucleic Acid Amplification (NAA) Testing Algorithm for *M. tuberculosis* complex

SPECIMEN CRITERIA

A. Primary Specimens	B. Sediments
Sputum, tracheal aspirate, or bronchial wash Specimen free of visible blood Specimen must be processed within 24 hrs of collection Specimens submitted to WSLH must be received within 24 hrs of collection. Specimens received on Saturday are not processed until Monday and therefore unacceptable for MTD testing. Specimen stored @ 2-8 degrees C	Sediments of sputum, tracheal aspirate, or bronchial wash Sediment must be from a specimen free of visible blood Sediment from specimen decontaminated within 24 hrs of collection using NALC-NaOH or NaOH method Sediments submitted to WSLH must be received in time to be tested within 72 hrs of decontamination. Test is not performed on Saturday or Sunday. Sediment stored @ 2-8 degrees C

NOTE: *All specimens for NAA will be tested for inhibitory substances that prevent nucleic acid amplification and may give false negative results.*

A. Smear Positive Specimens

1. First specimen is NAA-positive **Patient can be presumed to have TB.**
2. First specimen is NAA-negative

a. Inhibitors are NOT detected
Test 1 to 2 additional specimens collected on different days.
Patient can be presumed to have non-tuberculous mycobacteria if a second specimen is smear-positive, NAA-negative, and no inhibitors are detected

b. Inhibitors are detected
NAA test is of no diagnostic help. Presence of inhibitors in specimen is reported. One to two additional specimens collected on different days can be tested. If inhibitors are detected in follow-up specimen(s), NAA test is of no diagnostic help. Culture results are necessary to determine presence or absence of M. tuberculosis.

B. Smear Negative Specimens

1. First specimen is NAA-positive

Test 1 to 2 additional specimens collected on different days.
Patient can be presumed to have TB if a subsequent specimen is NAA-positive.

2. First specimen is NAA-negative

a. Inhibitors are NOT detected

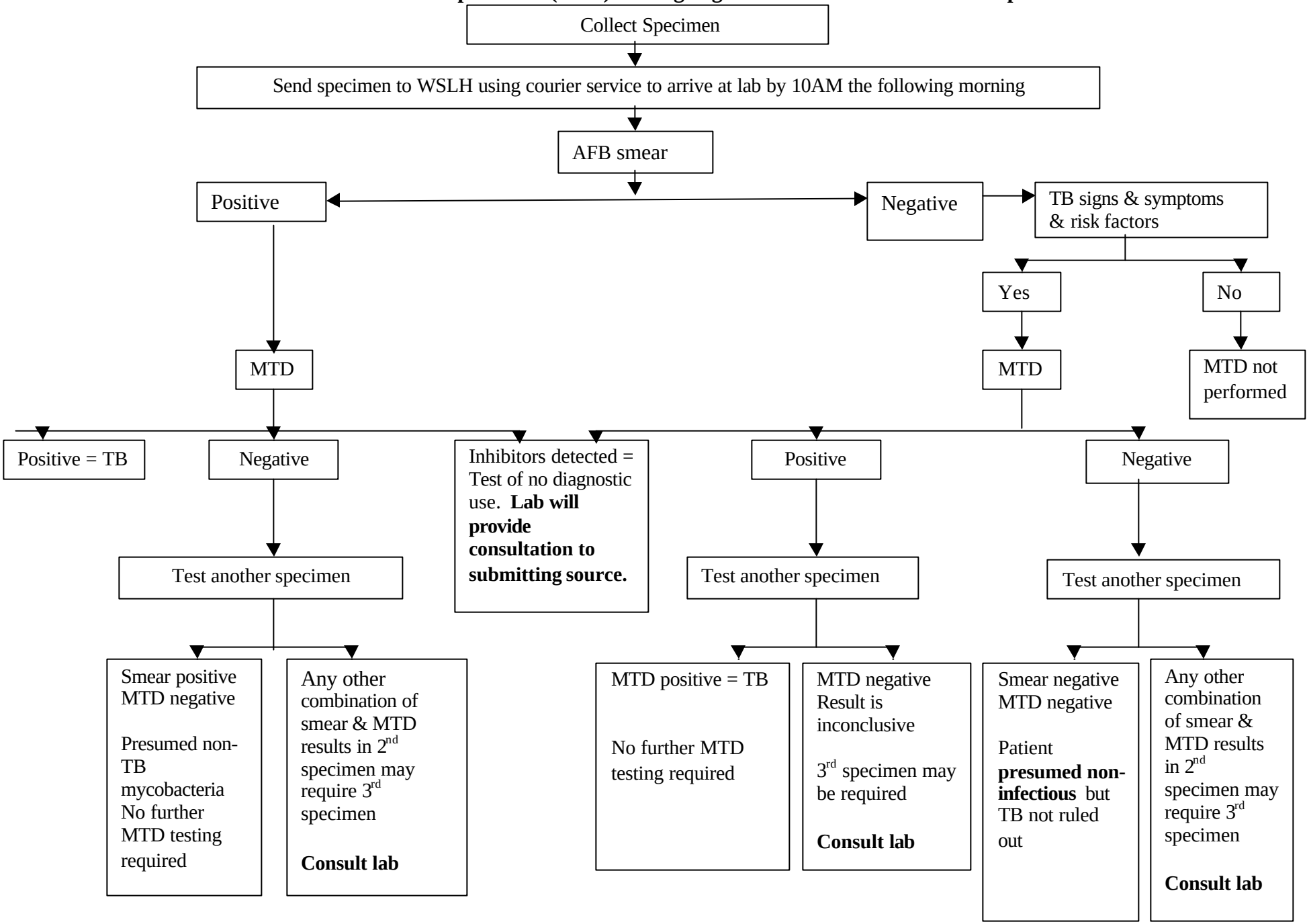
Test an additional specimen collected on a different day.
Patient can be presumed to be non-infectious if second specimen is also smear negative, NAA-negative, and does not contain inhibitors, but negative NAA result does not exclude the possibility of active pulmonary TB.

b. Inhibitors are detected

NAA test is of no diagnostic help. Presence of inhibitors in specimen is reported. One to two additional specimens collected on different days can be tested. If inhibitors are detected in follow-up specimen(s), NAA test is of no diagnostic help. Culture results are necessary to determine presence or absence of *M. tuberculosis*

C. If repeat NAA testing fails to verify initial NAA test results, the clinician must rely on clinical judgement in decisions regarding anti-TB therapy, further diagnostic work-up, and patient isolation.

Nucleic Acid Amplification(NAA) Testing Algorithm for *M. tuberculosis* complex



Accessing Services and Resources for Persons with Tuberculosis

Culture Results

1. Receive culture results considering the following information

    a. Positive results (*M.tuberculosis* complex) are usually available within 21 days
    b. Negative results are available in 6-8 weeks.
    c. This procedure determines the presence or absence of viable mycobacteria. If present, the species must be identified (*M. tuberculosis, M. avium*, etc.)
    d. The WSLH identification procedure uses High Performance Liquid Chromatography (HPLC). Other laboratories may also use genetic probe kits and/or biochemical testing.

2. Evaluate culture results with the following criteria:

    a. *"M. tuberculosis* complex" confirms TB.
    b. A preliminary result of "**non-TB mycobacteria** identification pending" **rules out TB**. Specific species identification will be reported later.
    c. A culture identified as non-TB mycobacteria (e.g. *M. avium*) usually rules out TB, unless the physician feels TB may also be present in the patient. Refer to the non-tuberculosis mycobacteria chart from the Epinet Manual for significance of specific non-tuberculosis mycobacterial identification.
    d. "Negative for mycobacteria" means no mycobacteria grew in the specimen, the culture is considered negative.

3. Receive drug susceptibility results considering the following information:

    a. The WSLH performs drug susceptibility tests on the initial isolate from patients with cultures positive for M. tuberculosis complex.
    b. Drug susceptibility results for M. tuberculosis complex are usually available within 35 days of sample submission.
    c. The WSLH uses the Bactec method for the following drugs: isoniazid, rifampin, streptomycin, ethambutol, and pyrazinamide.
    d. Isolates showing resistance to any of the first-line anti-TB medications are further tested using the agar dilution method for ethionamide, cycloserine, capreomycin, ciprofloxacin, and amikacin.

4. Evaluate drug susceptibility results and compare to patient's current regimen. Verify the patient is taking at least 2 medications to which the organism is susceptible.

    5. Discuss changes in regimen according to the susceptibility results with the physician (adding medications, changing medications, discontinuing medications). Refer to appropriate health department case management policies, procedures and practices for regimen adjustments/physician's orders.

Laboratory Test Quick reference

Test	Techniques	Specimen type	Turn Around Time
Smear	Fluorochrome acid-fast	Any clinical specimen	Within 24 hours of receipt in lab
Culture / Identification	Bactec, Septi-Chek, Midget, ESP, BacT-Alert / Nucleic Acid Probes HPLC	Any clinical specimen	Negative result: 6-8 weeks Positive result: within 21 days of receipt in lab
Nucleic Acid Amplification	PCR, MTD	Sputum or bronchial wash received within 24 hours of collection OR Sediment from sputum or bronchial wash that was initially processed within 24 hours of collection	Within 24 hours of smear result
Drug susceptibility testing	Bactec, conventional agar dilution	Any clinical specimen Automatically done on initial isolates of *M. tuberculosis* complex.	Within 35 days of receipt of specimen (TB positive cultures)

DNA Fingerprinting

1. Call the WI TB Program for consultation when considering whether DNA fingerprinting should be performed on an isolate of *M. tuberculosis*. Note the following information:

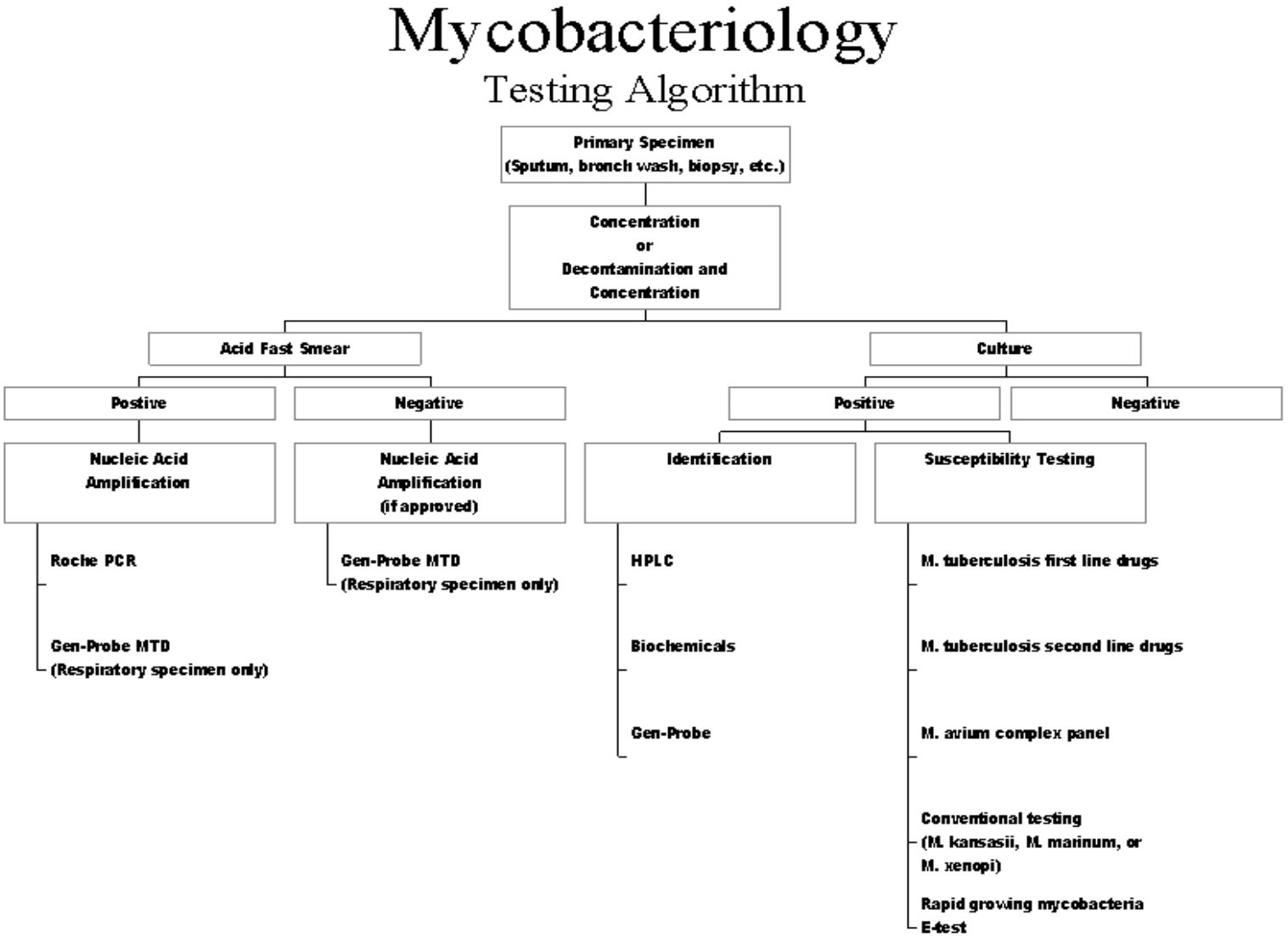
   - DNA fingerprinting may be used to investigate tuberculosis outbreaks, laboratory cross-contamination (false-positive cultures), and tuberculosis transmission.
   - Linkage between patients is determined based on matching fingerprint patterns and epidemiologic information.

2. Use the following table as a guideline to determine how long to wait for results before calling the WSLH. Note: the "submitting source" is the agency listed on the requisition form.

WSLH AFB Results Notification Quick Reference

Test	Results phoned ASAP	Hard copy lab report mailed
Smear	Positive results to submitting source and WI TB Program	**Positive results** - same day to submitting source and WI TB Program, WI TB Program forwards copy to LHD **Negative results** -within 1 working day to submitting source
MTD	All results to submitting source and WI TB Program	**Positive results** - same day to submitting source and WI TB Program, WI TB Program forwards copy to LHD **Negative results** -within 1 working day to submitting source and WI TB Program, WI TB Program forwards copy to LHD
Culture	Positive results to submitting source and WI TB Program	**Positive results** - same day to submitting source and WI TB Program, WI TB Program forwards copy to LHD **Negative results** -within 1 working day to submitting source
Drug susceptibility	Resistant results to submitting source and WI TB Program	**Resistant results** - same day to submitting source and WI TB Program, WI TB Program forwards copy to LHD **Sensitive results** -within 1 working day to submitting source and WI TB Program, WI TB Program forwards copy to LHD
DNA fingerprinting	Decided on case-by-case basis	All results to WI TB Program, WI TB Program forwards matching information to LHD

To inquire about results for reports not yet received, call the WSLH microbiology department at 608-262-1618.


Mycobacteriology
Testing Algorithm
Primary Specimen
(Sputum, bronch wash, biopsy, etc.)
Concentration
or
Decontamination and
Concentration
Acid Fast Smear
Culture
Postive
Negative
Positive
Negative
Nucleic Acid
Amplification
Nucleic Acid
Amplification
(if approved)
Identification
Susceptibility Testing
Roche PCR
Gen-Probe MTD
(Respiratory specimen only)
Gen-Probe MTD
(Respiratory specimen only)
HPLC
Biochemicals
Gen-Probe
M. tuberculosis first line drugs
M. tuberculosis second line drugs
M. avium complex panel
Conventional testing
(M. kansasii, M. marinum, or
M. xenopi)
Rapid growing mycobacteria
E-test

Liver Function Testing

Using the WSLH for fee-exempt testing of liver function for patients with TB infection or disease **and no third party payment source**.

1. Collection kits

    a. Order collection kits by calling the WSLH number for clinical supplies: (800) 862-1088, or (608) 265-2966. Operators are available to take telephone orders Monday through Friday from 7:45 a.m. to 3:30 p.m. Specify kit #22A. Store the kits at room temperature at the health department until the expiration date (marked on the Vacutainer blood collection tube).

    b. Obtain specimen collection materials from another source (local hospital, clinic, or physician's office) if no kits are available at the health department and specimen collection must occur prior to receipt of kits from WSLH. Assemble the following materials: sterile Vacutainer (red/gray) containing SST gel, a container label, 2 plastic zipper bags, paper towel, mailing box, packing material, and sealing tape.

2. Order requisition forms pre-printed with the health department fee exempt account number, as needed, by calling 1-800-862-1088.

3. Contact the WI TB Program with questions or concerns regarding guidelines for baseline and follow-up liver function monitoring. Refer to local health department policies, procedures, and practices for liver function monitoring protocols and obtain medical orders as needed.

4. Verify patient currently has no third party source of payment for liver function tests. Verify patient does not qualify for the Medicaid Tuberculosis Related Benefit (MA-TR Benefit).

5. Collect (or arrange collection of) serum specimen according to health department policies, procedures, and practices. Specimen may be submitted as serum in a sterile plastic vial or in a serum separator tube.

6. Send the specimen to the laboratory as soon as possible. Specimens received more than three days after collection may produce inaccurate results.

7. Write the patient's name and date collected on the container label and affix securely.

8. Complete a test request form using the local health department fee exempt account number. One form is required per specimen. Liver function tests are not listed on any WSLH request form. Write the type of test requested under the box titled "Other Tests." "ALT" is the most common liver function test requested/performed. Other liver function tests may be obtained by physician request (e.g. AST, Bilirubin, etc.).

9. Wrap the specimen container in absorbent material (such as a paper towel). Place the wrapped specimen container in zipper portion of a biohazard bag (or other plastic zipper bag labeled "biohazard") and zip close. Place the request form in the rear pouch of the biohazard

bag or in a separate zipper bag. Place the closed bag(s) in a styrofoam or other mailing container and seal with tape. Label the mailing container as "clinical specimen."

10. Address and mail the package to:
    State Laboratory of Hygiene, Room 121
    465 Henry Mall
    Madison, WI 53706

11. Receive results from the laboratory by mail within 1 week of sample submission. Call the WSLH Hepatitis Unit at 608/262-2302 if results are needed sooner or the hard copy report is delayed. ALT results are available the day after receipt.

12. Interpret the results based on normal range as defined by the laboratory or the kit manufacturer. The normal range for ALT as defined by the kit manufacturer is 8.0-51.0 IU/L. Follow health department policies, procedures, or practices for clinical management of patients with elevated liver function tests.

13. Submit requests for fee exempt liver function testing by the WSLH as ordered by the patient's physician according to the following maximum submission frequency:

    - Baseline and up to 3 follow-up tests for individuals without identified risk factors for hepatoxicity
    - Monthly liver function testing for patients with identified risk factors for hepatoxicity
    - Repeat testing at 2-week intervals for patients with elevated liver function tests and/or patients who are on the 2-month rifampin/pyrazinamide (RIF/PZA) regimen.

    Clinical monitoring of the person on medications is the primary factor in making decisions about medication regimens. Monitoring of laboratory results, when indicated, may assist with decision-making, but laboratory results are of no value in the absence of nursing assessments.

14. Contact the WSLH Hepatitis Unit for additional information 608-262-2302

HIV Testing

Using the WSLH for fee-exempt HIV testing for patients with TB infection or disease.

1. Facilitate HIV evaluation for all patients with latent TB infection or active TB disease because of the serious patient implications caused by the interaction between HIV and TB. HIV infection increases the probability that latent TB infection will progress to active TB disease. The immune response to TB infection or disease enhances HIV replication and may accelerate the natural progression of HIV infection. [*Resource: Centers for Disease Control and Prevention. Prevention and treatment of tuberculosis among patients infected with human immunodeficiency virus: principles of therapy and revised recommendations. MMWR 1998;47(No. RR-20):6.*]

2. Determine whether the health department is designated as a Counseling and Testing Services (CTS) site.

    a) If the health department is designated as a CTS site, use Wisconsin AIDS/HIV Program resources to provide HIV antibody testing, following appropriate CTS policies, procedures, and practices.

    b) If the health department is NOT designated as a CTS site, use the fee-exempt testing information that follows.

3. Order WSLH Virus-Chlamydia-Rickettsia requisition forms pre-printed the health department fee exempt account numbers as needed by calling 1-800-862-1088.

4. Determine which HIV testing procedure will be used based on the following information:

    a) **HIV-1/HIV-2 Combination Antibody Serum Screen (WSLH test code 99).** This test includes the HIV-1/HIV-2 EIA screening assay, and as appropriate the HIV-1 confirmatory Western Blot, HIV-2 EIA, and HIV-2 Western Blot.

    b) **Oral Fluid Vironastika HIV-1 Microelisa system/Western Blot** (Order under "Other Tests" box and indicate HIV-1 Oral Fluid Test) This test includes the HIV-1 EIA screening assay, and as appropriate the confirmatory HIV-1 Western Blot. Testing may be requested when use of needles would be unsafe - as in some field testing venues; when blood draw is difficult or clients are reluctant about having their blood drawn; or when staff are not trained in phlebotomy. **This test is not licensed to be used for children under the age of 13 years of age. Staff using this test must be trained in the use of the specimen collection device.** Call the AIDS/HIV Program for further information 608-267-3583.

5. Provide HIV prevention counseling that supports behavior change reducing an individual's risk for HIV infection, as appropriate. Health department staff who provide partner counseling and referral services (PCRS) should assume lead responsibility in assuring the quality of services provided with HIV testing (including counseling) are maintained.

6. Collection for the serum screen:

    a) Order test kits as needed by calling the toll-free number for clinical supplies: (800) 862-1088, or (608) 265-2966. Operators are available to take telephone orders Monday through Friday from 7:45 a.m. to 3:30 p.m. Specify kit #22A for the serum screen. Store the kits at room temperature at the health department until the expiration date (marked on the Vacutainer blood collection tube).

    b) Obtain specimen collection materials from another source (local hospital, clinic, or physician's office) if no kits are available at the health department and specimen collection must occur prior to receipt of kits from WSLH. Assemble the following materials: sterile Vacutainer (red/gray) containing SST gel, a container label, 2 plastic zippered bags, paper towel, mailing box, packing material, and sealing tape.

    c) Refer to local health department policies, procedures, and practices regarding HIV testing and obtain medical orders as needed.

    d) Contact the health department PCRS staff and/or the AIDS/HIV Program with questions or concerns.

    e) Collect (or arrange collection of) the appropriate specimen (blood/serum) according to health department specimen collection policies, procedures, and practices.

    f) Write the patient's name and date collected on the container label and affix securely.

    g) Complete a test request form using the local health department fee exempt account number. One form is required per specimen. Include the patient risk information **"TB Related" in the "Additional" category at the top half of the form**. Check test #99: "HIV-1/HIV-2 Combination Antibody Serum Screen."

    h) Wrap the specimen container in absorbent material (such as a paper towel). Place the wrapped specimen container in zipper portion of a biohazard bag (or other plastic zipper bag) and zip closed. Place request form in the rear pouch of the bag or into a second zipper bag in the mailing container. Place the bag and its contents in a styrofoam or other mailing container and seal with tape. Label the mailing container as "clinical specimen."

7. Collection for the oral fluids test:

    a) Order test kits as needed by calling the toll-free number for clinical supplies: (800) 862-1088, or (608) 265-2966. Operators are available to take telephone orders Monday through Friday from 7:45 a.m. to 3:30 p.m. Specify kit #22C-Bulk for the oral fluids test. Store the kits at room temperature at the health department until the expiration date (marked on the collection vial).

    b) Refer to local health department policies, procedures, and practices regarding HIV testing and obtain medical orders as needed.

c) Contact the health department PCRS staff and/or the AIDS/HIV Program with questions or concerns.

d) Follow appropriate health department policies, procedures, and practices as well as AIDS/HIV Program guidelines for collecting and submitting oral fluid specimens for HIV testing.

e) Write the patient's name and date collected on the container label and affix securely.

f) Complete a test request form using the local health department fee exempt account number. One form is required per specimen. Include the patient risk information **"TB Related" in the "Additional" category at the top half of the form**.

g) Write "HIV-1 Oral Fluid Test" under the box titled "Other Tests," since there is no test code for the Oral Fluid Vironastika HIV-1 Microelisa system/Western Blot. Check "Body Fluid" under Specimen Type and write "oral".

h) Contact the health department partner counseling and referral services (PCRS) staff and/or AIDS/HIV Program 608/267-3583 for further information about the Oral Fluid test.

i) Wrap the specimen container in absorbent material (such as a paper towel). Place the specimen vial in the zipper portion of a biohazard bag (or other plastic zipper bag) and zip closed. Place request form in the rear pouch of the bag or a second zipper bag in the mailing container. Place the bag and its contents in a styrofoam or other mailing container and seal with tape. Label the mailing container as "clinical specimen."

8. Address and mail the package to:

   State Laboratory of Hygiene, Room 121
   465 Henry Mall
   Madison, WI 53706

9. Notify the health department PCRS staff of sample submission. HIV results will be mailed within 2 weeks of sample submission **to the person listed as the HIV partner counseling and referral contact at the health department**.

Medical Assistance (MA) Benefits for Persons with Tuberculosis (TB)

	TB-Related Services (MA TR Benefit) (for direct/clinical services)	Case Management (for care coordination)
Eligibility	**Note: these income guidelines are specific to the TR Benefit.** 1.) Individuals who meet Supplemental Security Income (SSI) program financial requirements: ▪ a gross income of no more than $1,145* per month and ▪ assets of no more than $2,000 2.) Individuals with TB infection or disease documented by any of the following: ▪ the individual is infected with latent or active TB; ▪ the individual has a positive tuberculin skin test; ▪ the individual has a negative tuberculin skin test, but a positive sputum culture; ▪ the individual tests negative for TB, but based on a physician's judgment, requires TB-related drug and/or surgical therapy; or ▪ based on a physician's judgment, the individual requires testing to confirm the presence (or absence) of the TB organism.	1.) Individuals eligible for MA are eligible for Case Management. 2.) Individuals with TB infection or disease documented by any of the following: ▪ a positive TB skin test (if the skin test was done more than six months before the date case management was initiated, the provider must document that the recipient has not been treated or still requires treatment) ▪ a positive sputum culture for the TB organism within the past six months ▪ a physician's certification that the individual requires TB-related drug/or surgical therapy (even when the TB test is negative) ▪ a physician's order for testing to confirm the presence (or absence) of the TB organism ▪ a TB-related diagnosis by a physician
Covered Services	▪ Laboratory services, including services to diagnose and confirm presence of infection. A physician's name must be listed on the billing form. ▪ X-ray Services, including services to diagnose and confirm the presence or absence of disease. ▪ Directly Observed Therapy (DOT) ▪ TB Symptoms and Treatment Monitoring ▪ Patient Education and Anticipatory Guidance	Coordination of services rather than provision of services. These are activities, which help MA recipients identify their needs, manage and gain access to necessary medical, social, rehabilitation, vocational, educational and other services. Including: ▪ Assessment ▪ Case Plan Development ▪ Ongoing monitoring and service coordination
Becoming a Provider	If currently a PNCC Provider &/or HealthCheck Provider can bill MA under either one of these. If not an MA provider, request a HealthCheck Screening Certification Packet for billing TB Services by calling EDS at 1-800-947-9627.	Request certification materials to apply for Provider Type 90 (Case Management) by calling EDS at 1-800-947-9627. Must identify target populations will be serving. If currently certified as case management provider, must request "change request" form for target population changes .
Reimbursement	The maximum allowable fee for PHN services is $36.77/hr.** There are no copayment requirements for TB services.	Hourly rate: $40.28** Federal Government reimbursement is: $23.68/hr.** Remainder is the share the certified agency must contribute to the services as matching funds.
Allowable Providers	Physicians Pharmacies Outpatient Hospitals Family Planning Clinics Nurse Practitioners Physician Assistants Federally Qualified Health Care Centers (FQHCs) Local Health Departments ETC.	Targeted Case Management Agencies - Qualified public agencies and independent living centers.

*Changes every January **Rates current as of 2001 subject to change with Medicaid changes. Check Medicaid web site for the current information at www.dhfs.state.wi.us/medicaid1/maxfees/maxfee.htm or call (800) 947-9627.
This information is adapted from the *Wisconsin Medicaid Updates 96-03/96-08* and *96-14*.

VII. References Used for State Guideline Development

[*The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy and procedure document.*]

1. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395

2. American Thoracic Society. **Treatment of tuberculosis and tuberculosis infection in adults and children.** American Journal of Respiratory and Critical Care Medicine, 1994; 149: 1359-74.

3. American Thoracic Society. 1997. **Supplement: Diagnosis and Treatment of Disease Caused by Nontuberculous Mycobacteria**. Am. J. Respir. Crit. Care Med. 156(2): S1-S25

4. CDC Division of AIDS, STD and TB Laboratory Research, Tuberculosis/Mycobacteriology Branch, www.cdc.gov/ncidod/dastlr/TB/TBpublications.htm

5. California Department of Health Services and Executive Committee of the California Tuberculosis Controllers Association. **Guidelines for Follow-Up & Assessment of Persons with Class B1/B2 TB.** 8/10/99

6. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know**. Fourth Edition, 2000.

7. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**. MMWR April, 2000;49 (No. RR-6).

8. Centers for Disease Control and Prevention. **Improving Patient Adherence to Tuberculosis Treatment.** 1994.

9. Centers for Disease Control and Prevention. **Forging Partnerships to Eliminate Tuberculosis**. 1995.

10. Centers for Disease Control and Prevention. **NIOSH guide to the selection and use of particulate respirators certified under 42 CFR 8**4. 1996.

11. Centers for Disease Control and Prevention. **Self-Study Modules on Tuberculosis**. Modules 1-5, 1995. Modules 6-9, 2000.

12. Chin, J, ed. **TUBERCULOSIS**. In: Control of Communicable Diseases Manual. 17th ed. Washington, DC: American Public Health Association, 2000: 521-532.

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16. **Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health care facilities**, 1994. MMWR 1994; 43(RR-12).

17. Metchock, B.G., F.S. Nolte and R.J. Wallace. 1999. **Mycobacterium. *In* Manual of Clinical Microbiology**, p399-437. 7th Ed. Murray, P.R., E.J. Baron, M.A. Pfaller, F.C. Tenover and R.H. Yolken (ed). ASM Press, Washington, D.C.

18. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Patient Care**, 1997.

19. New Jersey Medical School National Tuberculosis Center, **Tuberculosis Glossary**, 1995

20. North Carolina Division of Epidemiology, Department of Health and Human Services. **North Carolina Tuberculosis Policy Manual**. 1997.

21. Pickering, L., ed. **Diseases Caused by Nontuberculous Mycobacteria**. In: 2000 Red Book: Report of the Committee on Infectious Diseases, 25th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2000, 613-618.

22. Pickering, L.K., ed. **Tuberculosis**. In: 2000 Red Book: Report of the Committee on Infectious Diseases. 25th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2000, 593-613.

23. **"Tuberculosis"** DPH Disease Fact Sheet Series, POH 4432. (http://www.dhfs.state.wi.us/healthtips/BCD/Tuberculosis.htm).

24. **TB Fact Sheet Series** found at http://www.dhfs.state.wi.us/dph_bcd/TB/Resources/TB_resources2.htm

    Sputum Conversion during TB Treatment, (POH 7131)
    Rifater and Rifamate in the Treatment of TB (POH 7133)
    Tuberculin Skin Testing for Suspected TB (POH 7134)
    The Importance of Rifampin (POH 7135)
    False-Positive Cultures for *Mycobacterium tuberculosis* (POH 7137)

25. Wayne, L.G. and R.C. Good, **The "Atypical" Mycobacteria: Recognition and Disease Association.** CRC Critical Rev. Micro. 12:185-222.

26. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases,** Chapter 145.

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32. Wolinsky, E. 1992. State of the art clinical article: **Mycobacterial Diseases Other Than Tuberculosis**. Clin. Infect. Dis. 15:1-12

33. **World Wide Web addresses**, National Model TB Centers & CDC:

    Harlem Model Center – www.harlemtbcenter.org
    New Jersey Model Center – www.umdnj.edu/ntbc
    San Francisco Model Center – www.nationaltbcenter.edu
    Centers for Disease Control and Prevention, CDC, Atlanta – www.cdc.gov

Supplement One to **Accessing Services and Resources for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI)**,
a Guideline for Establishing Effective Policies, Procedures and Practices

Interjurisdictional Tuberculosis Notification Form

effective January 1, 2003

This supplement replaces portions of Wisconsin's best practice guideline **"Accessing Services and Resources for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI)"**

The **Interjurisdictional Tuberculosis Notification Form (DPH 42010)** has been implemented to streamline the paperwork and the process of transferring care to other health departments. This replaces the CDC Interstate Notification Form and makes the writing of a summary letter unnecessary unless additional information must be explained that cannot be conveyed on the form.

In the procedure portion of the Accessing Services and Resources guideline, the use of the summary letter is described. [This information is likely to found on or near pages 30 through 33 of your procedure.] In sections A., 7., d. and e., the **Interjurisdictional Tuberculosis Notification Form** replaces writing the summary letter. In section 7., j., the **Interjurisdictional Tuberculosis Notification Form** replaces the CDC Interstate Notification Form.

Use this form to summarize the individual's data and provide any additional, client-specific information that will ensure successful follow up for the person in the new location. Continue to make a telephone contact with the local public health nurse in the receiving health department jurisdiction, as mentioned in Section 7.f. to ensure that successful public health follow up will occur.

As this tool becomes more wide-spread in use, the number of persons walking in to health departments after they are out of medication should diminish. If we in Wisconsin continue to take a leading role in practice methods that provide continuity of care, we inspire others to do the same.

Please call the TB Program at 608-266-9692 if you have any questions or concerns or if you need further assistance in using the guideline, or the supplement or in carrying out the referral process.

Supplement Two to **Accessing Services and Resources for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI)**, a Guideline for Establishing Effective Policies, Procedures and Practices

Important Considerations when Using RIF-PZA for LTBI Treatment

effective November 19, 2002

CDC has revised their recommendations for the use and clinical monitoring of the rifampin-pyrazinamide treatment regimen for latent tuberculosis infection (LTBI). These changes are indicated due to fatal and severe liver injuries associated with this regimen. Please review the following information carefully and ensure their medical provider is aware of these changes. **Face-to-face monitoring for medication side effects is crucial to quality patient care for anyone on treatment for LTBI.**

1. Exercise extreme caution when using a rifampin and pyrazinamide (RIF-PZA) regimen in those who are currently taking medications associated with liver injury or in those with a history of alcoholism, even if alcohol consumption is stopped during treatment.

2. RIF-PZA is NOT recommended for persons with underlying liver disease or for those who have had an INH-associated liver injury.

3. Educate providers to ensure that the dosage of PZA is at the lowest therapeutic, deliverable level, keeping in mind that tablets contain 500 mg.

4. **Deliver no more than two weeks of RIF-PZA at a time.**

5. Perform an in-person reassessment of patients taking RIF-PZA **every two weeks throughout treatment** for adherence, tolerance, and adverse effects. (Note: The clinical condition of the person may indicate more frequent monitoring.) At each visit, instruct the patient, in a language they understand, to stop taking RIF-PZA immediately and seek medical consultation if abdominal pain, emesis, jaundice, or other hepatitis symptoms develop. Health care provider continuity is recommended for monitoring.

6. Provide or arrange for serum aminotransferase (AST and/or ALT) and bilirubin measurements at baseline and every two weeks throughout treatment for patients taking RIF-PZA.

7. **Stop treatment with RIF-PZA and do not resume** with any of these findings:
   A serum bilirubin greater than normal range, aminotransferase (AST or ALT) greater than five times the upper limit of normal range in a person without symptoms, or aminotransferase (AST or ALT) greater than normal range when accompanied by symptoms of hepatitis.

8. When performing the in-person reassessment at the end of treatment for patients taking RIF-PZA**,** document clinical condition and treatment completion.

Recommended reading:
Update: Fatal and Severe Liver Injuries Associated with Rifampin and Pyrazinamide for the Treatment of Latent Tuberculosis Infection, and Revisions in American Thoracic Society/CDC Recommendations - United States, 2001."
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5034a3.htm

"Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection"
http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4906a1.htm

"Fatal and Severe Hepatitis Associated With Rifampin and Pyrazinamide for the Treatment of Latent Tuberculosis Infection - New York and Georgia, 2000 "
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5015a3.htm